Reregistration Eligibility Decision (RED) for Triethylene Glycol

September 2003

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA739-R-05-002
September 2005

Reregistration Eligibility Decision For Triethylene Glycol

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (EPA) has completed its review of the available data on the antimicrobial triethylene glycol. The Reregistration Eligibility Decision (RED) was approved in the form of a decision memorandum which summarized the regulatory decision for triethylene glycol on September 30, 2003.

Based on the Agency's review, the Reregistration Eligibility Decision (RED) and risk management decision with its associated human health and environmental risk assessments are now being published. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting documents for triethylene glycol will be available to the public in EPA's Pesticide Docket **OPP-2005-0250** at: http://www.epa.gov/edockets.

Please note that the attached RED document pertains only to triethylene glycol and presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to triethylene glycol alone. This document also contains product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Currently, there are no generic data requirements. For product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that triethylene glycol is eligible for reregistration. Sections IV and V of this RED document describe product-specific data requirements.

If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, Heather Garvie, at (703) 308-0034. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY DECISION
for
Triethylene Glycol
List C
CASE 3146

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
September 26, 2005

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
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, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
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	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
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.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern

LOD	Limit of Detection
LOAEL	Lowest Observed Adverse 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.
mg/kg/day	Milligram Per Kilogram Per Day
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.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
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
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
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.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
g/g	Micrograms Per Gram
g/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its human health and environmental review for triethylene glycol and is issuing its risk management decision. The Agency has decided that triethylene glycol is eligible for reregistration. This Reregistration Eligibility Decision (RED) addresses the use of triethylene glycol as a bacteriostat (against odor-causing bacteria) for air sanitization and deodorization. In combination with other active ingredients, it is used as a fungicide, virucide and miticide for disinfection of hard, non-porous surfaces and as an insecticide (against lice) by direct application to caged birds and to the cage. For these uses, triethylene glycol is formulated primarily as a pressurized liquid. This document also addresses the exposures from the use of this pesticide as an inert ingredient. As an inert ingredient, triethylene glycol facilitates delivery of formulated pesticide chemical products that are used as herbicides, fungicides, insecticides, growth regulators and attractants on a wide variety of agricultural commodities. This RED reassesses the exemption from the requirement for a tolerance for these uses. This tolerance exemption is listed in 40 CFR 180.920 (69 FR 23124, Apr. 28, 2004).

In addition to the above, triethylene glycol is approved by the Food and Drug Administration (FDA) as a preservative for food packaging adhesives as listed in 21 CFR 175.105. Currently, however, there are no EPA registered products for this use. Triethylene glycol also has an indirect food additive regulation [21 CFR 177.1200 (4/1/04)] for its use as a plasticizer in cellophane. This use is regulated by the Food and Drug Administration (FDA).

Overall Risk Summary

Hazard Profile/Human Health Risk

Based on a review of the available toxicology data, the Agency has concluded that triethylene glycol is of very low toxicity by the oral, dermal, and inhalation routes of exposure. The toxicology database is adequate to characterize the hazard of triethylene glycol, and no data gaps have been identified. There are no indications of special sensitivity of infants or children resulting from exposure to triethylene glycol. Therefore, the FQPA Safety Factor has been removed (i.e., reduced to 1X) for triethylene glycol. The Agency has not identified toxicological endpoints of concern for the active and the inert uses of triethylene glycol. Therefore, a quantitative human health risk assessment was not conducted for this RED document. The Agency has no risk concerns for triethylene glycol with respect to human exposure.

Environmental Risk

The Agency has relied on open literature data that characterizes the fate properties of triethylene glycol. The results of these studies indicate that triethylene glycol is miscible in water, mobile in soils and stable to abiotic degradation hydrolysis and soil and aquatic photolysis. Biodegradation is expected to proceed rapidly in surface waters.

Ecological effects data were previously waived due to the use of triethylene glycol as an indoor microbiocide, its high volatility, and known low toxicity (it is a preferred solvent for aquatic organism toxicity tests). Data obtained from published studies provide additional confirmation of the low toxicity of the compound to fish and aquatic invertebrates. The Agency has no risk concerns for triethylene glycol with respect to non-target organisms. The Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for TEG.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing triethylene glycol.

Summary of Mitigation Measures

The Agency has determined that triethylene glycol is eligible for reregistration. Since no risks of concern were identified, no specific mitigation measures are needed for triethylene glycol.

Data Requirements

No additional confirmatory data is required to complete the reregistration of triethylene glycol. However, product specific data is required for all products containing triethylene glycol as described in Section V of this document.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the Agency. Reregistration involves a thorough review of the scientific database 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 criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require a tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in the tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency s human health and ecological review and the Reregistration Eligibility Decision for triethylene glycol.

Triethylene glycol is used as a bacteriostat (against odor-causing bacteria) for air sanitization and deodorization. In combination with other active ingredients, it is used as a fungicide, virucide and miticide for disinfection of hard, non-pourous surfaces and as an insecticide (against lice) by direct application to caged birds and bird cages. This document also addresses the exposures and risks from the use of this pesticide as an inert ingredient. As an inert ingredient, triethylene glycol facilitates delivery of formulated pesticide chemical products that are used as herbicides, fungicides, insecticides, growth regulators and attractants on a wide variety of agricultural commodities.

The Agency has concluded that the FQPA Safety Factor for triethylene glycol should be removed (equivalent to 1X) because there is no pre- or post-natal evidence of increased susceptibility for infants and children following exposure to triethylene glycol.

The review summarized in this document concern only potential exposures from the use of the active ingredient triethylene glycol and its use as an inert ingredient. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has

followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for triethylene glycol and any other substances. Triethylene glycol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that triethylene glycol has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of triethylene glycol. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for triethylene glycol referenced in this RED. Related documents are available in the Public Docket at http://www.epa.gov/edocket.

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of triethylene glycol, and its regulatory history. Section III gives an overview of the revised human health and environmental assessments based on the data available to the Agency. Section IV presents the reregistration eligibility and risk management decisions. Section V summarizes procedures for the product-specific data call-in (PDCI). Finally, the Appendices contain all use patterns eligible for reregistration, bibliographic information, generic data requirements and studies used to make the reregistration decision, related documents and how to access them, and Data Call-In (DCI) information.

II. CHEMICAL OVEVIEW

A. Regulatory History

Triethylene glycol was first registered in 1947 for use in hospitals as an air disinfectant. At one point, there were approximately 105 pesticide chemical companies having active triethylene glycol registrations. Many of these registrations were canceled over the years and more recently, the majority of the remaining producers of triethylene glycol formulated pesticide products are being represented by a consortium called the CSPA (Consumer Specialty Products Association) Glycols Joint Venture. The member companies currently represented by this consortium are: Amrep, Inc., Chase Products Co., Medo Industries, Inc., S.C. Johnson & Son, Waterbury Companies, Inc., Speer Products, Inc. and Quest Chemical Corporation.

B. Chemical Identification

Triethylene Glycol:

Common Name:	Triethylene Glycol
Chemical Name:	Triethylene Glycol
Chemical family:	None
Case number:	3146
CAS registry number:	112-27-6
OPP chemical code:	083501
Empirical formula:	$C_6H_{14}O_4$
Molecular weight:	150.20 g/mol
Trade and other names:	TEG
Manufacturers:	CSPA Glycols Joint Venture companies (S.C. Johnson & Son, Inc., Waterbury Companies, Inc, Amrep, Inc., Speer Products, Inc., Quest Chemical Corporation, Medo Industries, Inc.
Specific Gravity:	1.1274
Solubility:	Highly miscible in water

	Soluble in alcohol, benzene, toluene, sparingly soluble in ether and insoluble in petroleum ether
Boiling Point:	285 ^{o} C, (at 760 mm Hg) 165 ^{o} C at 14 mm Hg.
Melting Point:	- 5 ^{o} C (- 7 ^{o} C)[1]
Vapor Pressure:	< 0.01 mm Hg at 20 ^{o} C (0.00132 mm Hg at 25 ^{o} C)[1]
Structure:	$OH-CH_2-CH_2-O-CH_2-CH_2-O-CH_2-CH_2-OH$

C. Use Profile

The following is information on the currently registered uses of triethylene glycol products and an overview of use sites and application methods. A detailed table of the uses of triethylene glycol eligible for reregistration is contained in Appendix A.

Type of Pesticide: Bacteriostat

Summary of Use Sites:

Indoor Non-Food: Triethylene glycol is used on the following use sites: air treatment (eating establishments, hospital, commercial, institutional, household, bathroom, transportational facilities); medical premises and equipment, commercial, institutional and industrial premises and equipment; laundry equipment; hard non-porous surface treatments (bathroom facilities); automobiles; air conditioning filters; bird (caged) animal treatment; pet bird cages; environmental inanimate hard surfaces; garbage containers/storage

Target Pests: Odor-causing bacteria

Inert Uses: As an inert ingredient, triethylene glycol facilitates delivery of formulated pesticide chemical products that are used as herbicides, fungicides, insecticides, growth regulators and attractants on various commodities.

Formulation Types: Pressurized liquid

Method and Rates of Application

Equipment: A wall mounted dispensing unit may be needed, depending on the type of application. Otherwise, the sanitizer is sprayed manually.

Method and Rate: For a wall mounted unit, the number of times the product is dispensed depends on the size of the room and should be used in accordance with the label directions.

If the product is dispensed from a metered dose aerosol can or from a hand held unit, as the amount dispensed will depend on the valve size utilized.

For an air sanitizer in a continuous action aerosol can, a one second spray is used for a 9 x 9 x 7 room.

Typically, an air sanitizer that is used manually is pointed toward the center of the room (12 x 12 x 9) and sprayed for ten seconds.

Use Classification: General use.

III. SUMMARY OF TRIETHYLENE GLYCOL ASSESSMENT

A. Human Health Assessment

1. Toxicity of TEG

A brief overview of the toxicity of triethylene glycol is presented below. Further details on the toxicity of triethylene glycol can be found in the supporting documentation for this RED. The Antimicrobials Division Toxicology Endpoint Selection Committee (ADTC) memorandum, the toxicology chapter for the RED and other supporting documentation are available on the Agency's website in the EPA Docket at http://www.epa.gov/edockets.

The toxicological database for triethylene glycol is currently comprised of published and unpublished studies either submitted to the Agency or obtained directly from the open literature. Although the available studies do not meet the requirements of the Agency s OPPTS harmonized test guidelines published in 1998, it was determined that these studies contain useful information that is adequate for hazard characterization of triethylene glycol. These acceptable non-guideline studies include acute, subchronic, chronic, developmental, and reproductive toxicity, carcinogenicity, mutagenicity, metabolism/pharmacokinetics and dermal absorption studies. Therefore, the Agency has determined that the toxicological database is complete and sufficient for reregistration.

Major features of the toxicology profile are presented below. Triethylene glycol is shown to be of low toxicity, with the exception of a dermal irritation study which was Toxicity Category III due to slight irritation.

Table 1. Acute Toxicity of Triethylene Glycol Technical

Guideline No./ Study Type	MRID	Results	Toxicity Category
870.1100 Acute Oral Toxicity	42814404 & open literature	LD_{50} = 15,000 –22,000 mg/kg	IV
870.1200 Acute Dermal Toxicity	—	Waived	—
870.1300 Acute Inhalation Toxicity	OTS: 527779-2	LC_{50} > 5.2 mg/L	IV
870.2400 Acute Eye Irritation	42814404	Mild eye irritation	IV
870.2500 Acute Dermal Irritation	42814404	Slight irritation	III
870.2600 Skin Sensitization	Open literature	Non-sensitizer	—

General Toxicity Observations

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to triethylene glycol. This conclusion is based on the results of toxicity testing of triethylene glycol in which dose levels near or above testing limits (as established in the OPPTS 870 series harmonized test guidelines) were employed in experimental animal studies and no significant toxicity observed.

Carcinogenicity Classification

A review of the available data has shown triethylene glycol to be negative for carcinogenicity in studies conducted up to the testing limit doses established by the Agency; therefore, no carcinogenic analysis is required.

Mutagenicity Potential

Triethylene glycol was tested for mutagenic or genotoxic potential and found to be negative in a battery of studies: a bacterial gene mutation assay using Salmonella typhimurium, and in vitro Chinese hamster ovary (CHO) mutation assay, an in vitro Chinese hamster ovary (CHO) chromosomal aberration assay and an in vitro sister chromatid exchange assay.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for triethylene glycol because there is no pre- or post-natal evidence for increased susceptibility following exposure. Further, the Agency has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to triethylene glycol based on the low toxicity observed in studies conducted near or above testing limit doses as established in the OPPTS 870 series harmonized test guidelines. Therefore, a quantitative risk assessment was not conducted for triethylene glycol.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. Since toxicological endpoints for risk assessment were not identified based on the available data, RfD's and PAD's have not been calculated for triethylene glycol.

4. Dietary and Residential Exposure

Dietary exposure (food and drinking water) could potentially occur from the use of triethylene glycol as a preservative in food packaging adhesives and from its use as an inert ingredient in agricultural pesticide formulations. Residential exposure could also potentially occur as a result of the use of triethylene glycol in and around the home as a sanitizer, disinfectant and bird treatment. However, risk estimates have not been calculated for potential exposures to triethylene glycol on food, in drinking water, or as a result of use in residential settings because there are no toxicological endpoints of concern according to a review of the available toxicity data.

5. Aggregate Exposure

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide and other non-occupational sources of exposure.

Since toxicological endpoints for risk assessment were not identified based on the available data, an aggregate risk assessment was not conducted for triethylene glycol.

6. Occupational Exposure

The occupational exposure assessment for triethylene glycol addresses potential exposures and risks to humans who may be exposed in occupational settings". An occupational and risk 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. For triethylene glycol, there is potential for exposure, however, there are no toxicological endpoints of concern, according to a review of the available toxicity.

7. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the 1993-1996 National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), the California Department of Pesticide Regulation, and the National Pesticide Telecommunications Network (NPTN). Although there are incidences that have been reported associated with TEG in the searched database, there is no one reported incident involving TEG as a single chemical exposure. Either no effects or minor effects are involved in these reported incidences. The other ingredients in combination with TEG may be the reasons for the symptoms that have been reported.

B. Environmental Assessment

A summary of the Agency's environmental review is presented below. For detailed discussions of all aspects of the environmental review, see the Product Chemistry, Environmental Fate and Toxicology chapters available on the Agency's website in the EPA Docket at: http://www/epa.gov/edockets.

1. Environmental Fate and Transport

Triethylene glycol is an aliphatic trihydroxy chemical and does not contain any hydrolyzable hydrogen. For this reason, the Agency granted a waiver from the aquatic hydrolysis study. For the reregistration process, however, the Agency has reviewed available open literature data and conducted the environmental fate assessment of triethylene glycol.
Based on a review of the open literature, triethylene glycol is miscible in water, mobile in soils and

stable to abiotic hydrolytic degradation as well as soil and aquatic photolysis. A number of River Dye-away tests (complete mineralization between 7 and 11 days) have shown that triethylene glycol degrades in soils in days (primary degradation) to weeks (complete mineralization). In addition, sludge innoculum studies indicate that triethylene glycol undergoes ready biodegradation. The use of sludge innoculum data as a surrogate for terrestrial soil metabolism is subject to considerable uncertainty because sludge innoculums tend to be acclimated to the introduction of organic substances more so than soils and the biomass on a per volume basis tends to be greater.

2. Ecological Risk

a. Toxicity (Hazard) Assessment

As a result of the Phase IV review of triethylene glycol for reregistration under FIFRA, ecological effects data requirements were waived due to its intended use as an indoor microbiocide, its high volatility, and known low toxicity (it is a preferred solvent for aquatic organism toxicity tests). Data obtained from published studies provide additional confirmation of the low toxicity of the compound to fish and aquatic invertebrates (Table 2). As mentioned earlier in this document, no toxicological endpoints were selected for risk assessment based on the available mammalian database.

Table 2. Ecotoxicity of Triethylene Glycol

Species	Percent Active Ingredient	Test Type	Toxicity	Reference
Mysid (*Mysidopsis bahia)*	99.9	96-hour static acute	LC50 = 11,000 ppm	MRID #40228401 (Mayer, 1986)
Sheepshead minnow (*Cyprinodon variegatus*)	99.9	96-hour static acute	LC50 = 48,000 ppm	MRID #40228401 (Mayer, 1986)
Bluegill sunfish (*Lepomis macrochirus*)	unknown	96 hour static acute	LC50 > 10,000 ppm	Verschuren, 1983
Menidia beryllina	unknown	96 hour static	LC50 > 10,000 ppm	Verschuren, 1983
Fathead minnow (*Pimephales promelas*)	unknown	96 hour flow-through	LC 50 59,900 - 77,400 ppm	Geiger et al., 1988

Adverse effects to nontarget organisms are not anticipated from the indoor use of triethylene glycol due to the low likelihood of exposure. The very low toxicity of the compound to aquatic organisms, as indicated by the high LC50 values in the table above, further supports the unlikelihood of adverse effects to fish and aquatic invertebrates.

b. Risk to Listed Species

Due to the low likelihood of exposure and low toxicity of triethylene glycol, the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

IV. RISK MANAGEMENT, REREGISTRATION AND TOLERANCE REASSESSMENT DECISION

A. Determination of Reregistration 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 to support reregistration of products containing triethylene glycol. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all supported products containing triethylene glycol.

The Agency has completed its assessment of the dietary, drinking water, residential, ecological and occupational risks associated with the use of pesticide products containing the active ingredient triethylene glycol. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of triethylene glycol to make a decision as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that triethylene glycol containing products are eligible for reregistration. Appendix A summarizes the uses of triethylene glycol that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of triethylene glycol, and lists the submitted studies that the Agency found acceptable.

B. Comments and Responses

Supporting documents for triethylene glycol were not issued for public comment per the Agency's public participation process because no toxicological endpoints were identified and, as such, a quantitative risk assessment was not conducted. To ensure that opportunity is presented to the public to comment on the risk management decisions and supporting documents for triethylene glycol, the Agency will implement a public comment period on this RED document.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. Risk Cup Determination

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to triethylene glycol. This conclusion is based on the results of toxicity testing of triethylene glycol in which dose levels near or above testing limits (as established in the OPPTS 870 series harmonized test guidelines) were employed in experimental animal studies and no significant toxicity observed. The Agency has concluded that the exemption from the requirement for a tolerance is appropriate and is considered reassessed as required by FQPA. An aggregate assessment was not conducted for exposures through food, drinking water and residential exposure since toxicological endpoints for

risk assessment were not identified based on the available data. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to triethylene glycol. This conclusion is based on the results of toxicity testing of triethylene glycol in which dose levels near or above testing limits (as established in the OPPTS 870 series harmonized test guidelines) were employed in experimental animal studies and no significant toxicity observed. The Agency has determined that the established exemption from the requirement for a tolerance for triethylene glycol meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of triethylene glycol. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of triethylene glycol.

Because no toxicological endpoints were identified for triethylene glycol, the Agency has determined that exposure to it does not result in human health effects of concern. Therefore a quantitative risk assessment was not necessary for this pesticide.

c. Determination of Safety to Infants and Children

EPA has determined that the established exemption from a requirement for a tolerance for triethylene glycol, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of triethylene glycol residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from triethylene glycol residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for triethylene glycol because there is no pre- or post-natal evidence for increased susceptibility following exposure.

d. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined

that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, triethylene glycol may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

Any risks summarized in this document are those that result only from the use of triethylene glycol. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for triethylene glycol. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Summary

The tolerance exemption for residues of triethylene glycol *per se* is established under 40 CFR 180.920 (69 FR 23124, Apr.28, 2004).

Tolerance Exemptions

The following tolerance exemption for triethylene glycol is listed in 40 CFR 180.920 (7/1/04):

Triethylene glycol is exempted from the requirement of a tolerance when used as an inert (or occasionally active) ingredient in pesticide formulations applied to growing crops only as a deactivator.

In addition to the above, triethylene glycol is approved by the Food and Drug Administration as a preservative for food packaging adhesives as listed in 21 CFR 175.105.

Triethylene glycol also has an indirect food additive regulation (21 CFR 177.1200) for its use as a plasticizer in cellophane. However, this use is regulated solely by the Food and Drug Administration (FDA).

a. Codex Harmonization

Currently there are no Codex MRLs established for triethylene glycol.

D. Regulatory Rationale

The Agency has determined triethylene glycol is eligible for reregistration. Based on the available data, the Agency has concluded that triethylene glycol exhibits low toxicity and exposures to triethylene glycol used as both an active or inert ingredient do not present risks of concern to the Agency. Therefore, no mitigation measures are necessary at this time.

1. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and

Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a “no effect” determination. Due to the low likelihood of exposure and low toxicity of triethylene glycol, the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

b. General Risk Mitigation

Triethylene glycol end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing triethylene glycol specific to federally listed species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. WHAT REGISTRANTS NEED TO DO

The Agency has determined that triethylene glycol is eligible for reregistration. No additional generic data are required at this time to support this decision.

For end use products containing the active ingredient triethylene glycol, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);

2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

4. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

5. the product-specific data responding to the PDCI.

Please contact Marshall Swindell at (703) 308-6341 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Marshall Swindell
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Marshall Swindell
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing-Use Products

There are no currently registered triethylene glycol manufacturing-use products.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of triethylene glycol for the above eligible uses has been reviewed and determined to be substantially complete. Therefore at this time, there are no generic data requirements.

B. End-Use Products

1. Additional Product-Specific and Efficacy 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. 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 the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

The Agency considers the terms "sanitizer" and "sanitization" to be public health claims, regardless of the use site or whether the specific organisms for which the product is efficacious against are identified or not. This policy was reiterated in the proposed Part 152/156 Antimicrobial Registration Requirements, 64 FR 50672-50730, September 17, 1999. Upon finalization of this proposed rulemaking, efficacy data will be required to support the continued use of the term "air sanitizer" on the product label.

Until the proposed Product Performance Guidelines for proposed Part 152/15 are finalized, testing requirements are being deferred for products of this type. Currently, efficacy requirements are satisfied by the chemical formula statement showing appropriate glycol content. For products containing at least 5% glycols (triethylene, dipropylene, and/or propylene glycols), quantitative chemical determinations must be performed, using an air sampling device, to show the concentration of glycol vapor achieved with the product in an enclosed experimental room or chamber when used as directed.

A product-specific data call-in, outlining specific data requirements, will be issued shortly. In the interim, no additional public health claims can be made unless supported by the appropriate efficacy data.

VI. APPENDICES

Appendix A: Use Patterns Eligible for Reregistration

Use Categories:
(1) Agricultural premises and equipment
(2) Food handling/ storage establishments premises and equipment
(3) Commercial, institutional and industrial premises and equipment
(4) Residential and public access premises
(5) Medical premises and equipment
(6) Human water systems
(7) Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(10) Wood preservatives
(11) Swimming pools
(12) Aquatic areas

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
1. Agricultural Premises and Equipment - no registered uses for this pattern				
2. Food Handling/Storage Establishments Premises and Equipment				
Air Treatment (Eating Establishments)	1. 10807-43 - pressurized liquid - automatic dispenser	1. 7 ounce product contains 3400 controlled sprays that will last for 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes (room size not specified)	1. information not given on label	1. do not use in nurseries or rooms where infants, ill or aged patients are confined; food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use

	2. 10807-37 & 10807-24 - pressurized liquid - manual spray	2. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	2. spray several times per day	2. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
3. Commercial, Institutional and Industrial Premises and Equipment				
Commercial Premises & equipment	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes; for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Shower Room Premises	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes; for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Air Treatment (Unspecified)	1. 9444-136- pressurized liquid - automatic dispenser	1. metered valve actuates every fifteen minutes - 7 ounce product treats a room up to 30 X 20 X 10	1. information not given on label	1. do not contaminate water, food or feed by storage or disposal
	2. 4822-293- pressurized liquid - manual spray	2. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9)	2. information not given on label	2. avoid contact with food and food utensils

Laundry Equipment	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Air Treatment (Locker Room)	1. 10807-43- pressurized liquid - automatic dispenser	1. 7 ounces of product contains 3400 controlled sprays that will last for 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes (room size not specified)	1. information not given on label	1. do not use in nurseries or rooms where infants, ill or aged patients are confined; food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
	2. 9444-19- pressurized liquid - automatic intermittent aerosol dispenser	2. 6.2 ounces treats 6,000 cubic feet of closed air space.	2. sprayed at intervals	2. do not contaminate water, food or feed
	3. 10807-37 & 10807-24- pressurized liquid - manual spray	3. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	3. spray several times per day	3. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use

Locker Room Premises	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes or for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Air Treatment (Institutional)	1. 51838-1 - ready to use solution- automatic dispenser operation	1. 7 ounce product for each 6,000 cubic feet of closed air space	1. product sprayed at intervals	1. avoid contamination of food
	2. 51838-1- pressurized liquid - for manual operation	2. fill average size room with mist (approximately 15 sprays)	2. repeat application several times daily	2. avoid contamination of food
	3. 10807-37 & 10807-24- pressurized liquid- manual spray	3. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	3. spray several times per day	3. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
	4. 4822-293- pressurized liquid - manual spray	4. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9)	4. information not given on label	4. avoid contact with food and food utensils

	5. 4822-531-pressurized liquid - wall mounted unit in continuous action aerosol can	5. one second spray for a 9.5 X 9 X 7 room	5. information not given on label	5. do not position near heat or electrical sources; do not spray directly onto surfaces; in case of contact with surfaces, wipe immediately with damp cloth.
	6. 44446-20-pressurized liquid - manual spray	6. spray for three seconds	6. information not given on label	6. wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet

	7. 4822-531-wall mounted unit in metered dose aerosol can or pressurized liquid - hand held unit	7. using a 120 l valve with .22 ounces of product: -1 time for 2.5 X 2.5 X 7 room -2 times for 4 X 3 X 7 room -3 times for 4.5 X 4 X 7 room -4 times for 5 X 5 X 7 room using a 185 l valve- -1 time for 3 X 3 X 7 room -2 times for 4.5 X 4 X 7 room -3 times for a 5.5 X 5 X 7 room 4 times for a 6 X 6 X 7 room	7. information not given on label	7. do not position near heat or electrical sources; do not spray directly onto surfaces; in case of contact with surfaces, wipe immediately with damp cloth.
	8. 10807-43-pressurized liquid - automatic dispenser	8. 7 ounce product contains 3400 controlled sprays that will last for 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes (room size not specified)	8. information not given on label	8. do not use in nurseries or rooms where infants, ill or aged patients are confined; food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use

Air Treatment (Commercial)	1. 51838-1-ready to use solution - for automatic dispenser operation	1. 7 ounce product for each 6,000 cubic feet of closed air space	1. product sprayed at intervals	1. avoid contamination of food
	2. 51838-1-ready to use solution - for manual operation	2. fill average size room with mist (approximately 15 sprays)	2. repeat application several times daily	2. avoid contamination of food
	3. 10807-43 - pressurized liquid-automatic dispenser	3. 7 ounce product contains 3400 controlled sprays that will last for 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes (room size not specified)	3. information not given on label	3. do not use in nurseries or rooms where infants, ill or aged patients are confined; food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
	4. 10807-37 & 10807-24-pressurized liquid - manual spray	4. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	4. spray several times per day	4. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use

	5. 9444-19 - Pressurized liquid - automatic intermittent aerosol dispenser	5. 6.2 ounces of product treats 6,000 cubic feet of closed air space.	5. sprayed at intervals	5. do not contaminate water, food or feed
	6. 4822-293 - pressurized liquid - manual spray	6. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9)	6. information not given on label	6. avoid contact with food and food utensils
	7. 44446-20- pressurized liquid - manual spray	7. spray for three seconds	7. information not given on label	7. wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
	8. 51838-2 - pressurized liquid - automatic dispenser	8. spray for one second toward center of average size room (10 X 14 X 8)	8. repeat application several times daily	8. spray away from drapes, walls, plastic, vinyl, painted or varnished surfaces
Air Treatment (Transp Facilities)	1. 51838-1- ready to use solution - for automatic dispenser	1. 7 ounces of product for each 6,000 cubic feet of closed air space	1. product sprayed at intervals	1. avoid contamination of food
	2. 4822-293- pressurized liquid - manual spray	2. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9	2. information not given on label	2. avoid contact with food and food utensils

	3. 10807-37 & 10807-24 - pressurized liquid - manual spray	3. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	3. spray several times per day	3. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
	4. 51838-1- ready to use solution - for manual operation	4. fill average size room with mist (approximately 15 sprays)	4. repeat application several times daily	4. avoid contamination of food
Air Treatment (Industrial)	1. 51838-1- ready to use solution - automatic dispenser	1. 7 ounces of product for each 6, 000 cubic feet of closed air space	1. product sprayed at intervals	1. avoid contamination of food
	2. 51838-1- ready to use solution - for manual operation	2. fill average size room with mist (approximately 15 sprays)	2. repeat application several times daily	2. avoid contamination of food
	3. 10807-37 & 10807-24- pressurized liquid - manual spray	3. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	3. spray several times per day	3. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use

	4. 10807-43-pressurized liquid - automatic dispenser	4. 7 ounces of product contains 3400 controlled sprays that will last for 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes (room size not specified)	4. information not given on label	4. do not use in nurseries or rooms where infants, ill or aged patients are confined; food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
4. Residential and Public Access Premises				
Air Treatment (Unspecified)	1. 9444-136-pressurized liquid - automatic dispenser	1. metered valve actuates every fifteen minutes - 7 ounce product treats a room up to 30 X 20 X 10	1. information not given on label	1. do not contaminate water, food or feed by storage or disposal
	2. 4822-293-pressurized liquid - manual spray	2. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9)	2. information not given on label	2. avoid contact with food and food utensils
Household (Premises & Contents)	44446-20-pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes or for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet

Air treatments (commercial/household)	4822-531-pressurized liquid - wall mounted unit in metered dose aerosol can or hand held unit	using a 120 l valve with .22 ounces of product: -1 time for 2.5 X 2.5 X 7 room -2 times for 4 X 3 X 7 room -3 times for 4.5 X 4 X 7 room -4 times for 5 X 5 X 7 room using a 185 l valve- -1 time for 3 X 3 X 7 room -2 times for 4.5 X 4 X 7 room -3 times for a 5.5 X 5 X 7 room 4 times for a 6 X 6 X 7 room	information not given on label	do not position near heat or electrical sources; do not spray directly onto surfaces; in case of contact with surfaces, wipe immediately with damp cloth.
Laundry Equipment	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toile
Automobiles	44446-20 - pressurized liquid - manual spray	spray into air conditioning system and spray for four to six seconds	information not given on label	shut off air conditioner after applying the product; wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet

Shower Room Premises	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes or for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Hard Nonporous Surface	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Environmental Inanimate Hard Surfaces	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Garbage Storage Premises & Containers	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes or for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
Bathroom Premises	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes or for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet

Air Treatment (Bathroom)	1. 10807-43-pressurized liquid - automatic dispenser	1. 7 ounces of product contains 3400 controlled sprays that will last for 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes (room size not specified)	1. information not given on label	1. do not use in nurseries or rooms where infants, ill or aged patients are confined; food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
	2. 9444-19-pressurized liquid - automatic intermittent aerosol dispenser	2. 6.2 ounce of product treats 6,000 cubic feet of closed air space.	2. sprayed at intervals	2. do not contaminate water, food or feed
	3. 44446-20-pressurized liquid - manual spray	3. spray for three seconds	3. information not given on label	3. wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet
	4. 10807-37-pressurized liquid - manual spray	4. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	4. spray several times per day	4. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use

	5. 51838-1- pressurized liquid - manual operation	5. fill average size room with mist (approximately 15 sprays)	5. repeat application several times daily	5. avoid contamination of food
	6. 4822-293 - pressurized liquid - manual spray	6. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9	6. information not given on label	6. avoid contact with food and food utensils
	7. 4822-531- pressurized liquid - wall mounted unit in continuous action aerosol can	7. one second spray for a 9.5 X 9 X 7 room	7. information not given on label	7. information not given on label
	8. 10807-24 - pressurized liquid- manual spray	8. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	8. spray several times per day	8. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use

	9. 4822-531-wall mounted unit in metered dose aerosol can or pressurized liquid - hand held unit	9. using a 120 l valve with .22 ounces of product: -1 time for 2.5 X 2.5 X 7 room -2 times for 4 X 3 X 7 room -3 times for 4.5 X 4 X 7 room -4 times for 5 X 5 X 7 room using a 185 l valve- -1 time for 3 X 3 X 7 room -2 times for 4.5 X 4 X 7 room -3 times for a 5.5 X 5 X 7 room 4 times for a 6 X 6 X 7 room	9. information not given on label	9. information not given on label
Locker Room Premises	44446-20 - pressurized liquid - manual spray	spray surface until completely wet and allow to remain wet for 10 minutes or for air sanitization spray for three seconds	information not given on label	wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet

Air Treatment (Locker Room)	1. 10807-43- pressurized liquid - automatic dispenser	1. 7 ounces of product contains 3400 controlled sprays that will last for 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes (room size not specified)	1. information not given on label	1. do not use in nurseries or rooms where infants, ill or aged patients are confined; food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
	2. 9444-19- pressurized liquid - automatic intermittent aerosol dispenser	2. 6.2 ounces treats 6,000 cubic feet of closed air space.	2. sprayed at intervals	2. do not contaminate water, food or feed
	3. 10807-37 & 10807-24- pressurized liquid - manual spray	3. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	3. spray several times per day	3. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
Birds (Caged) (Animal Treatment)	11715-20 - pressurized liquid- manual spray	spray lightly with one burst of 2 or 3 seconds	no more than 2 times per week	information not given on label

Pet Bird Cages (Enclosed Premise Treatment)	11715-20 - pressurized liquid-manual spray	thoroughly spray perches and cage	regular intervals	information not given on label
Air Treatment (Pet Kennels & Enclosed Premise Treatment)	1. 4822-531-pressurized liquid - wall mounted unit in metered dose aerosol can or hand held unit	1. using a 120 l valve with .22 ounces of product: -1 time for 2.5 X 2.5 X 7 room -2 times for 4 X 3 X 7 room -3 times for 4.5 X 4 X 7 room -4 times for 5 X 5 X 7 room using a 185 l valve- -1 time for 3 X 3 X 7 room -2 times for 4.5 X 4 X 7 room -3 times for a 5.5 X 5 X 7 room 4 times for a 6 X 6 X 7 room	1. information not given on label	1. do not position near heat or electrical sources; do not spray directly onto surfaces; in case of contact with surfaces, wipe immediately with damp cloth.

	2. 4822-531-pressurized liquid - wall mounted unit in continuous action aerosol can	2. one second spray for a 9.5 X 9 X 7 room	2. information not given on label	2. information not given on label
	3. 4822-293-pressurized liquid - manual spray	3. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9	3. information not given on label	3. avoid contact with food and food utensils

5. Medical premises and equipment				
Air treatments (sickroom)	1. 4822-531-pressurized liquid - wall mounted unit in metered dose aerosol can or hand held unit	1. using a 120 l valve with .22 ounces of product: -1 time for 2.5 X 2.5 X 7 room -2 times for 4 X 3 X 7 room -3 times for 4.5 X 4 X 7 room -4 times for 5 X 5 X 7 room using a 185 l valve- -1 time for 3 X 3 X 7 room -2 times for 4.5 X 4 X 7 room -3 times for a 5.5 X 5 X 7 room 4 times for a 6 X 6 X 7 room	1. information not given on label	1. do not position near heat or electrical sources; do not spray directly onto surfaces; in case of contact with surfaces, wipe immediately with damp cloth.
	2. 4822-531-pressurized liquid - wall mounted unit in continuous action aerosol can	2. one second spray for a 9.5 X 9 X 7 room	2. information not given on label	2. information not given on label

Air treatment (hospital)	1. 51838-2 - pressurized liquid- manual spray	1. spray for one second toward center of average size room (10 X 14 X 8)	1. repeat application several times daily	1. spray away from drapes, walls, plastic, vinyl, painted or varnished surfaces
	2. 51838-1- ready to use solution - automatic dispenser	2. 7 ounces of product for each 6, 000 cubic feet of closed air space	2. product sprayed at intervals	2. avoid contamination of food
	3. 51838-1- ready to use solution - for manual operation	3. fill average size room with mist (approximately 15 sprays)	3. repeat application several times daily	3. avoid contamination of food
	4. 10807-37 & 10807-24 - pressurized liquid - manual spray	4. spray the room until a light fog forms - spray 6 to 8 seconds in an average room (10 X 10)	4. spray several times per day	4. food, food contact surfaces and utensils should be protected from exposure to the spray or rinsed with potable water before use
	5. 4822-293 - pressurized liquid - manual spray	5. spray upward in center of room for 10 seconds in average room of 12 X 12 X 9	5. information not given on label	5. avoid contact with food and food utensils
	6. 44446-20- pressurized liquid - manual spray	6. spray for three seconds	6. information not given on label	6. wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet

	7. 9444-19 - pressurized liquid - automatic intermittent aerosol dispenser	7. 6.2 ounces of product treats 6,000 cubic feet of closed air space	7. sprayed at intervals	7. do not contaminate water, food or feed
Hospital (Premises and Materials)	44446-20- pressurized liquid -manual spray	decontamination against HIV-1 of surfaces/objects soiled with blood/body fluids - 1800 ppm of active quaternary water for a contact time of 10 minutes at room temperature - use a 10 minute contact time for disinfection against all other bacteria and fungi claimed	information not given on label	dispose of infectious materials according to federal, state and local regulations

Appendix B: Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide To Appendix B

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Triethylene Glycol (TEG). These requirements apply to TEG in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

   (1) Agricultural premises and equipment
   (2) Food handling/ storage establishments premises and equipment
   (3) Commercial, institutional and industrial premises and equipment
   (4) Residential and public access premises
   (5) Medical premises and equipment
   (6) Human water systems
   (7) Materials preservatives
   (8) Industrial processes and water systems
   (9) Antifouling coatings
   (10) Wood preservatives
   (11) Swimming pools
   (12) Aquatic areas

4. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identify each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
TECHNICAL GRADE ACTIVE INGREDIENT (TGAI) CHEMISTRY				
830.1550	61-1	Product Identity and Composition	2,3,4,5	42814401 and 42211801
830.1600 830.1620 830.1650	61-2A	Starting Materials and Manufacturing Process	2,3,4,5	42814401
830.1670	61-2B	Formation of Impurities	2,3,4,5	42814401
830.1700	62-1	Preliminary Analysis	2,3,4,5	42814402
830.1750	62-2	Certification of Limits	2,3,4,5	42814402
830.1800	62-3	Analytical Method	2,3,4,5	42814402
830.6302	63-2	Color	2,3,4,5	42814403 and 42211801
830.6303	63-3	Physical State	2,3,4,5	42814403 and 42211801
830.6304	63-4	Odor	2,3,4,5	42814403 and 42211801
830.7200	63-5	Melting Point	2,3,4,5	not required
830.7220	63-6	Boiling Point	2,3,4,5	42814403
830.7300	63-7	Density	2,3,4,5	42814403

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7840 830.7860	63-8	Solubility	2,3,4,5	42814403
830.7950	63-9	Vapor Pressure	2,3,4,5	42814403
830.7370	63-10	Dissociation Constant in Water	2,3,4,5	waived
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	2,3,4,5	42814403
830.7000	63-12	pH	2,3,4,5	42814401; 42211801; 42814403
830.6313	63-13	Stability	2,3,4,5	42814401; 42211801; 42814403
830.6314	63-14	Oxidizing/Reducing Action	2,3,4,5	42814403
830.6315	63-15	Flammability	2,3,4,5	42814403
830.6316	63-16	Explodability	2,3,4,5	42814403
830.6317	63-17	Storage Stability	2,3,4,5	42814403
830.7100	63-18	Viscosity	2,3,4,5	42814403
830.6319	63-19	Miscibility	2,3,4,5	42814403
830.6320	63-20	Corrosion Characteristics	2,3,4,5	42814403

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.6321	63-21	Dielectric breakdown voltage	2,3,4,5	42814403
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test - Quail/duck	All	waived due to high volatility and low toxicity
850.1075	72-1 C	Fish Acute Toxicity - Rainbow Trout	All	waived due to high volatility and low toxicity
850.1075	72-1 C	Fish Acute Toxicity - Fathead Minnow	All	waived due to high volatility and low toxicity
850.1010	72-2A	Acute Aquatic Invertebrate Toxicity	All	waived due to high volatility and low toxicity

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
non-guideline	non-guideline	Other published literature/extraneous submissions: 1. Mysid (*Mysidopsis bahia)*- 96-hour static acute; toxicity LC50 = 11,000 ppm 2. Sheepshead minnow (*Cyprinodon variegatus*) - 96-hour static acute; toxicity LC50 = 48,000 ppm 3. Bluegill sunfish (*Lepomis macrochirus*) - 96 hour static acute; toxicity LC50 > 10,000 ppm *4. Menidia beryllina* - 96 hour static; toxicity LC50 > 10,000 ppm 5. Fathead minnow (*Pimephales promelas*) - 96 hour flow-through; toxicity - LC 50 59,900 - 77,400 ppm	n/a	The below list not required for current uses; available in open literature: 1. 40228401 2. 40228401 3. Open Literature 4. Open Literature 5. Open Literature
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	2,3,4,5	42814404 & Open Literature
870.1200	81-2	Acute Dermal - Rabbit	2,3,4,5	waived
870.1300	81-3	Acute Inhalation – Rat	2,3,4,5	OTS 527779-2 (Nachreiner, D.J., 1991)

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.2400	81-4	Acute Eye Irritation - Rabbit	2,3,4,5	42814404
870.2500	81-5	Acute Skin Irritation - Rabbit	2,3,4,5	42814404
870.2600	81-6	Dermal Sensitization	2,3,4,5	42814404 & Open Literature
870.3100	82-1a	90-Day Oral Subchronic -Rat	2,3,4,5	Open Literature & OTS 0527779-1 (Union Carbide, 1989 and Union Carbide, 1990)
870.3250	82-3*	21-Day Subchronic Dermal	2,3,4,5	42814404 & Open Literature
870.3465	82-4*	90-Day Subchronic Inhalation	2,3,4,5	OTS 0537563-1 (Norris, J. and W. Kintigh, 1994 & Sun, J. and W. Kintigh, 1993)
870.4100	83-1a	Chronic Toxicity - rat	2,3,4,5	satisfied by guideline 870.4300
870.4100	83-1b	Chronic Toxicity - non-rodent	2,3,4,5	42814404 & Open Literature
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity - rat	2,3,4,5	42814404 & Open Literature

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.3700	83-3a	Prenatal Developmental Toxicity - Rat	2,3,4,5	42814404 & OTS 7527779-4 (Union Carbide, 1991)
870.3700	83-3b	Prenatal Developmental Toxicity - Rabbit	2,3,4,5	42814404
870.3800	83-4**	Reproduction and fertility effects - Rat	2,3,4,5	42814404 & Open Literature
870.5100	84-2	Bacterial Reverse Mutation Test	2,3,4,5	OTS 50527779-1
870.5300	84-2	In Vitro Mammalian Cell Gene Aberration Test	2,3,4,5	OTS 50527779-1
870.5375	84-2	In Vitro Mammalian Chromosome Aberration Test	2,3,4,5	OTS 50527779-1
870.5900	84-2	In Vitro Sister Chromatid Exchange	2,3,4,5	OTS 50527779-1
870.7485	85-1	Metabolism and Pharmocokinetics	2,3,4,5	42814404
*For guidelines 82-3 and 82-4, at least one is required to be fulfilled; not both (for both food and non-food uses). **Only required for food use.				
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis of Parent and Degradates	2,3,4,5	waived

Please Note: Although the Open Literature studies do not satisfy any of the Agency's testing guideline requirements, this information is considered adequate for characterizing the potential hazard from exposure to triethylene glycol. Therefore, no additional mammalian toxicity data will be required at this time.

Appendix C: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4:00 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.epa.gov/edocket

These documents include:

- Triethylene Glycol (TEG): Antimicrobials Division's Review of the Disciplinary Sciences for Issuance of the Reregistration Eligibility Decision (RED) Document. Reregistration Case No.: 3146, PC Code: 083501. CAS Registry No.: 112-27-6

- Triethylene Glycol- Revised Report of the Antimicrobials Division Toxicology Endpoint Selection Committee. PC Code 083501, Case 3146, Antimicrobials Division, 11/21/05, Timothy F. McMahon, Ph.D., Chair, ADTC

- Product Chemistry Science Chapter. PC Code 083501, Case 3146, Antimicrobials Division, 8/13/03, A. Najm Shamim, Ph.D., Chemist

- Environmental Fate Studies and Environmental Fate Assessment. PC Code 083501, Case 3146, Antimicrobials Division, 8/13/03, A. Najm Shamim, Ph.D.

- Revised Toxicology Disciplinary Chapter. PC Code 083501, Case 3146, Antimicrobials Division, 10/11/05, Michelle Centra

- Occupational and Residential Exposure. PC Code 083501, Case No. 3146, Antimicrobials Division, 5/24/05, Timothy Leighton, Environmental Scientist

- Ecological Hazard and Environmental Risk Characterization. PC Code 083501, Case 3146, Antimicrobials Division, 8/4/04, Kathryn Montague, M.S.

- Review of Phase IV Response Submissions in Support of FIFRA 88. Memorandum: G. Reddy, 12/22/93

- Triethylene Glycol: Incident Report Assessment for the Reregistration Eligibility Decision (RED) Document. PC Code: 083501. Case No. 3146 (Memorandum: J. Chen, 9/22/03).

- Triethylene Glycol Estimated Drinking Water Concentrations (Memorandum: S. Abel, 9/26/03).

Appendix D: Bibliography Citations

MRID Number	Citation
40228401	Mayer, F.L. (1986) Acute Toxicity Handbook of Chemicals to Estuarine Organisms. Prepared by U. S. EPA Office of Research and Development, Environmental Research Laboratory, Gulf Breeze, FLA EPA/600/X-36/231.
42211801	Reed, G. (1992) Product Chemistry Data: Ozium Glycolized Air Sanitizer. Unpublished study prepared by Blue Coral, Inc. 10 p.
42814404	Davis, K.(1993) Compilation of Toxicology Data References for Triethylene Glycol: Lab Project Number: TEGTOX. Unpublished study prepared by RegWest Co. 131 p.
42814401	Davis, K. (1993) Product Chemistry Data of Triethylene Glycol: Lab Project Number: TEG61. Unpublished study prepared by RegWest Co. 6 p.
42814402	Davis, K. (1993) Product Chemistry Data of Triethylene Glycol: Lab Project Number: TEG62. Unpublished study prepared by RegWest Co. 13 p.
42814403	Davis, K. (1993) Physical & Chemical Characteristics of Triethylene Glycol: Lab Project Number: TEG63. Unpublished study prepared by RegWest Co. 91 p.

EPA ID Document Number	
OTS0527779-1	Guzzie, P., Slesinski, F. Frank, et al. (1986a) Triethylene Glycol Salmonella/Microsome (Ames) Bacterial Mutagenicity Assay. Bushy Run Research Center, Export, PA. Project Report 49-58. April 29, 1986. NTIS Report No. OTS0527779-1. Unpublished.
OTS0527779-1	Guzzie, P., Slesinski, F. Frank, et al. (1986b) Triethylene Glycol:*In vitro* Chromosome Aberration Study. Bushy Run Research Center, Export, PA. Project Report 49-82. July 1, 1986. NTIS Report No. OTS0527779-1. Unpublished.
OTS0527779-1	Slensinski, R., F. Frank, and P. Guzzie (1986a) Triethylene Glycol:*In vitro* Genotoxicity Studies: CHO/HGPRT Mutation Test; Sister Chromatid Exchange Assay. Bushy Run Research Center, Export, PA.

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OTS0527779-1 Union Carbide (1989) Triethylene Glycol: Fourteen-day Dietary Toxicity Study in Fischer 344 Rats. NTIS Report No. OTS0527779-1. Unpublished.

OTS0527779-1 Union Carbide (1990a) Triethylene Glycol: Ninety-day Dietary Toxicity Study in Fischer 344 Rats. NTIS Report No. OTS0527779-1. Unpublished.

OTS0527779-1 Union Carbide (1990b) Developmental Toxicity Study of Triethylene Glycol Administered by Gavage to CD-1 Mice. NTIS Report No. OTS0527779-1. Unpublished.

OTS0527779-2 Nachreiner, D.J. (1991) Triethylene Glycol (TEG) Acute Aerosol Inhalation Toxicity Test in Rats. Bushy Run Research Center; Project Report 53-139 (BRCC No. 90-22-40272), March 4, 1991; NTIS Report No. OTS0527779-2. Unpublished.

OTS0527779-4 Union Carbide (1991) Developmental Toxicity Study of Triethylene Glycol Administered by Gavage to CD (Sprague-Dawley) Rats. NTIS Report No. OTS0527779-4. Unpublished.

OTS0537563-1 Norris, J. and W. Kintigh (1994) Triethylene Glycol: Nine-day Aerosol Inhalation (Nose-only Exposure) toxicity study in Rats. Bushy Run Research Center, Union Carbide Corporation, Inc., Export, PA. Laboratory Project ID: 93U1293, October 26, 1994. NTIS Report No. OTS0537563-1. Unpublished.

OTS0537563-1 Sun, J. and W. Kintigh (1992) Triethylene Glycol: Nine-day Aerosol Inhalation study in Rats. Bushy Run Research Center, Union Carbide Chemicals and Plastics Company, Inc., Export, PA. Laboratory Project ID: 91U0027, December 14, 1992. NTIS Report No. OTS0537563-1 with cover letter dated 010693 (1992). Unpublished.

Open Literature Citations

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Budavari, S., M.J. O'Neill, A. Smith, and P.E. Heckelman (eds.)1989. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. Rahway (eleventh edition), NJ: Merck & Co., Inc.

Clayton, G.D. and F.E. Clayton (eds.). Patty's Industrial Hygiene and Toxicology: Volume 2A, 2B, 2C: Toxicology. 3rd ed. New York: John Wiley Sons, 1981-1982. 3839.

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Geiger, D.L., Call, D.J., and Brooke, L.T. (Eds). 1988. Acute Toxicities of Organic Chemicals to Fathead Minnows (Pimephales promelas). Vol. IV. Superior Wisconsin: University of Wisconsin-Superior. 131.

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McKennis, Jr., et al. (1962) The Excretion and Metabolism of Triethylene Glycol. Toxic.

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Robertson, O.H., et al. (1947) Tests for the Chronic Toxicity of Propylene Glycol and Triethylene Glycol on Monkeys and Rats by vapor inhalation and Oral Administration. J. Pharm. Exp. Ther., 91: 52.

Smyth, H.F. et al (1941) The single dose toxicity of some glycol derivatives. J. Ind. Hyg. Toxicol. 23(6): 259-268.

Stenger, E.G., er al. (1968) Zur Toxikologie des Triathylenglkol. Arzneimittel-Forsch, 18: 1536.

Verschuren, K. 1983. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co. 1153.

Supporting Documentation

NIH. 2003. NIH's Hazard Substances Databank (HSDB), A Database of the National Library of Medicine's TOXNET System. http://www.nih.gov/TOXNET

USEPA. 1997. Pesticide Handler Exposure Database (PHED, Version 1.1), Surrogate Exposure Guide; Estimates of Worker Exposure, May 1997.

USEPA. 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., to Julie Fairfax; dated November 4, 1999.

USEPA. 2003. Estimation of Physical/Chemical Properties Program. http://www.epa.gov/oppt/exposure/docs/episuitedl.htm

USEPA. 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, January 24, 04, Appendix A, Section IIB, pg.81. http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf

Appendix E: Generic Data Call-In

The Agency does not intend to issue a Generic Data Call-In at this time.

Appendix F: Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G: Batching of End-Use Products

Antimicrobial Division's Batching of Products Containing Triethylene Glycol as the Active Ingredient for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient triethylene glycol, the Agency has batched products which can be considered similar in terms of acute toxicity. (The PC Code of triethylene glycol is 083501; the CAS Number is 112-27-6.) Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), labeling (e.g., signal word, precautionary labeling, etc.) and acute toxicity data.

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

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single set of six acute toxicity studies to represent all the products within that batch. Registrants have the option of participating with all or some other registrants of products in their product's batch, to deal only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. <u>If a registrant chooses to generate the data for a batch, he or she must use one of the products within the batch as the test material.</u> If a registrant chooses to rely upon previously submitted acute toxicity data, he or she may do so provided that the data base is complete and valid by today's standards (see the attached acceptance criteria), the formulation tested is considered by EPA to be similar in terms of acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. <u>Registrants may not support their product using data conducted on a product from a different batch, unless this batching appendix specifically states so.</u> <u>The Antimicrobials Division must approve any new or canceled formulations (that were presented to the Agency after the publication of the RED) before data derived from them can be used to cover other products in a batch.</u> <u>Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number.</u> If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

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

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

If a registrant would like to have the batching status of a product reconsidered, they need to submit detailed information on their product, including a detailed rationale for the inclusion of their product into a batch. An MSDS for each “inert” ingredient should be included where possible. However, registrants and manufacturers should realize that the more unique their formulation is, the less likely it is to be able to batch that product. AD/PSB notes that there were no registered Technical Grade Active Ingredient (TGAI) products to be reviewed in this batching chapter.

Table 1 displays the batch for the active ingredient Triethylene Glycol.

Table 1.

Batch	Registration Number	Percent Active Ingredient
1	51838-1	Triethylene Glycol ... 4.4% Propylene Glycol ... 4.4%
	51838-2	Triethylene Glycol ... 4.4% Propylene Glycol ... 4.4%
2	4822-293	Triethylene Glycol ... 6.0%
	4822-531	Triethylene Glycol ... 6.0%

Table 2 lists the products in the "No Batch" group. These products can not be batched because they were not considered to be similar to other the products in terms of acute toxicity or because there was insufficient information available to assist in making the decision.

Table 2. The "No Batch Group" of Products Containing Triethylene Glycol as an Active Ingredient

Registration Number	Percent Active Ingredient
9444-19	Triethylene Glycol ... 6.000% Dipropylene Glycol ... 4.000% n-Alkyl dimethyl benzyl ammonium chloride ... 0.20%
9444-136	Triethylene Glycol ... 9.15% Dipropylene Glycol ... 3.43% n-Alkyl dimethyl benzyl ammonium chloride ... 0.17%
10807-24	Triethylene Glycol ... 4.5% Propylene Glycol ... 3.0% n-Alkyl dimethyl benzyl ammonium chloride ... 0.10%
10807-37	Triethylene Glycol ... 3.00% Dipropylene Glycol ... 3.00% n-Alkyl dimethyl benzyl ammonium chloride ... 0.10% n-Alkyl dimethyl ethylbenzyl ammonium chloride ... 0.10%
10807-43	Triethylene Glycol ... 7.7% Propylene Glycol ... 5.13% n-Alkyl dimethyl benzyl ammonium chloride ... 0.17%
11715-20	Triethylene Glycol ... 0.10% Propylene Glycol ... 0.10% Pyrethrins ... 0.09% Piperonyl butoxide ... 0.18% n-Octyl bicycloheptene dicarboximide ... 0.30%
44446-20	Triethylene Glycol ... 6.00% n-Alkyl dimethyl ammonium chloride ... 0.10% n-Alkyl dimethyl ethylbenzyl ammonium chloride ... 0.10% Isopropanol ... 50.20%

Appendix H: List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I: List of Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf

8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

a. 83-3 Label Improvement Program--Storage and Disposal Statements
b. 84-1 Clarification of Label Improvement Program
c. 86-5 Standard Format for Data Submitted under FIFRA
d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: http://npic.orst.edu/

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.