United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA-739-R-06-002
September 2006

Reregistration Eligibility Decision For Propylene Glycol and Dipropylene 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 (hereafter referred to as EPA or the Agency) has completed its review of the available data for the antimicrobials propylene glycol and dipropylene glycol. The Reregistration Eligibility Decision (RED) was approved in the form of a decision memorandum which summarized the regulatory decision for propylene glycol and dipropylene glycol on September 30, 2004.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) for propylene glycol and dipropylene glycol and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting documents for propylene glycol and dipropylene glycol will be available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2006-0831 at: www.regulations.gov.

Please note that the attached RED document pertains only to propylene glycol and dipropylene glycol. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to propylene glycol or dipropylene 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. Additionally, 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 propylene glycol and dipropylene glycol are 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, Michelle Centra, at (703) 308-2476. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

Betty Shackleford for

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY DECISION
for
Propylene Glycol and Dipropylene Glycol
List C
CASE 3126

Approved By:

Betty Shackleford for

Frank T. Sanders
Director, Antimicrobials Division
September 29, 2006

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC50	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD50	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure

MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protection factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for propylene glycol and dipropylene glycol and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products. As a result of this review, EPA has determined that products containing propylene glycol and dipropylene glycol alone are eligible for reregistration. Products containing propylene glycol and dipropylene glycol in combination with other active ingredients will be reregistered only when all of the active ingredients have been determined to be eligible for reregistration. That decision is discussed fully in 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 required 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 propylene and dipropylene glycol.

As active ingredients, propylene glycol and dipropylene glycol are formulated primarily as pressurized liquids and ready-to-use solutions. Propylene glycol is used in air sanitization and hard surface disinfection and dipropylene glycol is used in air sanitization. Pest (fleas, mites, red lice, and various bacteria and viruses) control for pets (cats, dogs, and birds) is also a major active use for propylene glycol. As an inert ingredient, propylene glycol is formulated into end-use agricultural and antimicrobial pesticide products whereas dipropylene glycol is formulated into pesticide products for use in agricultural settings. Products containing propylene glycol and dipropylene glycol in combination with other active ingredients will be reregistered only when all of the active ingredients have been determined to be eligible for reregistration. This document addresses the exposures and risks from the use of these pesticides as both active and inert ingredients in pesticide products.

The Agency has concluded that the FQPA Safety Factor for propylene glycol and dipropylene 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 either propylene or dipropylene 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 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 propylene or dipropylene glycol and any other substances. Neither propylene nor dipropylene glycol appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that propylene or dipropylene glycol have 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 propylene and dipropylene 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 these pesticides referenced in this RED. Related documents will be available in the Public Docket at www.regulations.gov.

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 propylene and dipropylene glycol, and their 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

Propylene glycol and dipropylene glycol were first registered in 1950 and 1959, respectively, by the FDA for use in hospitals as air disinfectants. At one point, there were approximately 190 pesticide chemical companies having active propylene or dipropylene glycol registrations. Many of these registrations were canceled over the years and more recently, the majority of the remaining producers of propylene and dipropylene 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., Beaumont Products, Inc., Chase Products, MEDO/SOPUS Products, Reckitt Benkiser, Inc., S.C. Johnson & Son, Inc., Wellmark International, and Waterbury Companies, Inc.

B. Chemical Identification

1. Propylene Glycol:

Common Name:	Propylene Glycol
Chemical Name:	1, 2-Propanediol or 1,2-hydroxypropane
Chemical family:	None
Case number:	3126
CAS registry number:	57-55-6
OPP chemical code:	068603
Empirical formula:	$C_3H_8O_2$
Molecular weight:	76.00 g/mol
Trade and other names:	Propylene glycol
Manufacturers:	CSPA Glycols Joint Venture (Amrep, Beaumont Products, Inc., Chase Products, MEDO/SOPUS Products, Reckitt Benkiser, Inc., S.C. Johnson & Son, Inc., and Waterbury Companies, Inc.
Specific Gravity:	1.038

Solubility:	Highly miscible in water
Boiling Point:	188 ^{o}C at 760 mm Hg
Melting Point:	N/A
Vapor Pressure:	0.04 – 0.08 mm Hg at 20 ^{o}C
Structure:	OH-CH_2-CH(OH)-CH_3

2. Dipropylene Glycol:

Common Name:	Dipropylene Glycol
Chemical Name:	Oxybispropanol
Chemical family:	None
Case number:	3126
CAS registry number:	25265-71-8
OPP chemical code:	068604
Empirical formula:	$C_6H_{14}O_3$
Molecular weight:	134.00 g/mol
Trade and other names:	Dipropylene glycol
Manufacturers:	CSPA Glycols Joint Venture (Waterbury Companies, Inc., and Beaumont Products, Inc.)
Specific Gravity:	1.038
Solubility:	Highly miscible in water
Boiling Point:	188 ^{o}C at 760 mm Hg
Melting Point:	N/A
Vapor Pressure:	0.04 – 0.08 mm Hg at 20 ^{o}C
Structure:	OH-CH_2-CH(OH)-CH_3

C. Use Profile

1. Propylene Glycol

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

Type of Pesticide: Bacteriostat, Fungistat

Summary of Use Sites:

Indoor Non-Food: Propylene 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; pet treatment, including cats, dogs, and caged birds; environmental inanimate hard surfaces; garbage containers/storage.

Target Pests: Odor-causing bacteria, Fleas, Mites, Red lice, Animal pathogenic bacteria (G- and G+ vegetative), Shigella bacteria, Pasteurella bacteria, Listeria bacteria, Herpes Simplex I and II, Animal viruses, Influenza Virus A2, Aspergillus Niger Fungus, Mold/Mildew, Pseudomonas SPP., Shigella Flexneri, Shigella Sonnei.

Inert Uses: As an inert ingredient, propylene glycol facilitates delivery of formulated pesticide chemical products that are used as herbicides, fungicides, insecticides, growth regulators and attractants on various commodities. It is also used in the formulation and repackaging of wood preservatives.

Formulation Types: Pressurized liquid, ready-to-use

Method and Rates of Application

Pet Treatment

For dogs, puppies, cats, kittens; hold spray container 4-6 inches away from animal and direct spray into fur, starting from tail. Rub spray down into fur so that skin is treated. For birds, hold spray bottle three feet from bird and spray lightly - one burst every two or three seconds. Apply no more that two times per week.

Air Sanitizer

Read the directions included with the automatic dispenser for proper installation of unit and refill. Remove cap from aerosol can and place in a sequential aerosol dispenser which

automatically releases a metered amount every 15 minutes. One unit should treat 6000 ft^3 of closed air space. Dispenser should be located at a height of eight feet and at a point where wind flow will carry the particles throughout the area. Each spray dose is 100 mg and the median particle size is 30 microns. For regular, non-metered applications, spray room until a light fog forms. To sanitize the air, spray 6 to 8 seconds in an average size room (10' x10').

Hard, Non-Porous Surface Disinfectant

Spray surface until thoroughly wet and let stand 10 minutes, then wipe with a dry paper towel. On non-porous surfaces, rinse surface with water. To sanitize non-porous surfaces, spray until wet. Let stand one minute, then wipe. To prevent mold and mildew on pre-cleaned non-porous surfaces, spray surface until wet. Allow to air dry. Repeat application on pre-cleaned surface at weekly intervals.

Table 1 lists the registrant and the respective EPA registration numbers for products containing propylene glycol.

Table 1. EPA Registration Numbers for Propylene Glycol Products

Use Category	Formulation	Registrant	EPA Registration Numbers
Air Sanitizer/ Disinfectant	Pressurized Liquid	S. C. Johnson & Son, Inc.*	4822-491
Air Sanitizer	Pressurized Liquid	Amrep, Inc.*	10807-24, 10807-37, 10807-43
Air Sanitizer	Pressurized Liquid	MEDO/SOPUS Industries, Inc.*	51838-1, 51838-2
Mite, flea, and Lice Control	Pressurized Liquid	Wellmark International *,**	2724-514, 2724-618, 2724-763, 2724-764

* Member companies of the GSPA Glycols Joint Venture.

** The insecticidal products containing propylene glycol in addition to other active ingredients will be reregistered only when all of the active ingredients have been determined to be eligible for reregistration.

Use Classification: General use.

2. Dipropylene Glycol

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

Type of Pesticide: Bacteriostat, Fungistat

Summary of Use Sites:

Indoor Non-Food: Dipropylene glycol is used on the following use sites: air treatment (eating establishments, hospital, commercial, institutional, household, bathroom)

Target Pests: Odor-causing bacteria, Animal pathogenic bacteria (G- and G+ vegetative), Animal viruses

Inert Uses: As an inert ingredient, dipropylene 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, ready-to-use

Method and Rates of Application

Air Sanitizer

As an air sanitizer, remove cap from aerosol can and place in a sequential aerosol dispenser which automatically releases a metered amount every 15 minutes. One unit should treat 6000 ft^3 of closed air space. Dispenser should be located at a height of eight feet and at a point where wind flow will carry the particles throughout the area. Each spray dose is 100 mg and the median particle size is 30 microns. Table 2 lists the registrant and the respective EPA registration numbers for products containing dipropylene glycol.

Use Classification: General use.

Table 2 lists the registrant and the respective EPA registration numbers for products containing dipropylene glycol.

Table 2. EPA Registration Numbers for Dipropylene Glycol Products

Use Category	Formulation	Registrant	EPA Registration Numbers
Air Sanitizer	Pressurized Liquid	Waterbury Companies, Inc.*	9444-19, 9444-136

* Member companies of the GSPA Glycols Joint Venture.

III. SUMMARY OF PROPYLENE GLYCOL AND DIPROPYLENE GLYCOL ASSESSMENT

A. Human Health Assessment

The Agency's use of human studies in the propylene glycol and dipropylene glycol assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

1. Toxicity of Propylene Glycol and Dipropylene Glycol

A brief overview of the toxicity of propylene glycol and dipropylene glycol is presented below. Further details on the toxicity of propylene glycol and dipropylene glycol can be found in the supporting documentation for this RED. The Antimicrobials Division Toxicology Endpoint Selection Committee (ADTC) memorandum and the toxicology chapter for the are available in EPA's Pesticide Docket, EPA-HQ-OPP-2006-0831 at www.regulations.gov.

The toxicological database for propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 acute toxicology profile for propylene glycol and dipropylene glycol are presented below in Table 3. Propylene glycol and dipropylene glycol are shown to be of low acute toxicity (Toxicity Category IV).

Table 3. Acute Toxicity of Propylene Glycol and Dipropylene Glycol Technical

Table 3. Acute Toxicity Profile of Propylene/Dipropylene Glycol			
Guideline	**Study Type**	**Results**	**Toxicity Category**
Propylene Glycol			
870.1100	Acute Oral - Rat	LD_{50} range = 8000 - 46000 mg/kg	IV
870.1100	Acute Oral - Mouse	LD_{50} range = 23000 - 24900 mg/kg	IV
870.1100	Acute Oral - Rabbit, Guinea pig	LD_{50} range = 18000 - 20000 mg/kg	IV
870.2400	Acute Eye Irritation - Rabbit	non irritant	IV
870.2500	Acute Skin Irritation - Rabbit		IV

Table 3. Acute Toxicity Profile of Propylene/Dipropylene Glycol			
		non irritant	
870.2600	Skin Sensitization	non sensitizer	N/A
Dipropylene Glycol			
870.1100	Acute Oral - Rat	LD_{50} > 5010 mg/kg	IV
870.1100	Acute Oral - Rat	LD_{50} range > 5000 to >15000 mg/kg	IV
870.1200	Acute Dermal - Rabbit	LD_{50} > 5010 mg/kg	IV
870.1200	Acute Dermal - Rabbit	LD_{50} > 2000 mg/kg	IV
870.1300	Acute Inhalation - Rat	LC_{50} > 2.34 mg/L	IV
870.2400	Acute Eye Irritation - Rabbit	slight irritant	IV
870.2400	Acute Eye Irritation - Rabbit	slight irritant	IV
870.2500	Acute Skin Irritation - Rabbit	non irritant	IV
870.2600	Skin Sensitization - Guinea Pig	non sensitizer	N/A

N/A = not applicable

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 propylene glycol and dipropylene glycol. This conclusion is based on the results of toxicity testing of propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol to be negative for carcinogenicity in studies conducted up to the testing limit doses established by the Agency; therefore, no further carcinogenic analysis is required.

Mutagenicity Potential

Propylene glycol and dipropylene glycol were 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 propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 propylene glycol and dipropylene 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, RfDs and PADs have not been calculated for propylene glycol and dipropylene glycol.

4. Dietary and Residential Exposure

Dietary exposure (food and drinking water) could potentially occur from the use of propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol in and around the home as a sanitizer, disinfectant and pet treatment. However, risk estimates have not been calculated for potential exposures to propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol.

6. Occupational Exposure

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

7. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to propylene glycol and dipropylene glycol. EPA consulted the following sources of information for human poisoning incidents related to propylene glycol and dipropylene glycol use: **(1) OPP Incident Data System (IDS)** - The Office of Pesticide Programs (OPP) **Incident Data System** contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; **(2) California Department of Pesticide Regulation (1982-2004)** – The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982. **(3) National Pesticide Information Center (NPIC)** - NPIC is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991. **(4) National Poison Control Centers (PCC)** (1993 – 1996).

Although there are incidents that have been reported associated with propylene glycol or dipropylene glycol, there is no one reported incident involving propylene glycol or dipropylene glycol as an individual chemical exposure. Either no effects or minor effects (nasal irritation and sensitization) involved in these reported incidents. Since propylene glycol and dipropylene glycol are often formulated with other active ingredients, reported symptoms may result from reactions to the other active ingredients or the combination of propylene glycol and dipropylene glycol with other ingredients.

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, Ecotoxicology, and Toxicology chapters available in EPA's Pesticide Docket, EPA-HQ-OPP-2006-0831 at www.regulations.gov.

1. Environmental Fate and Transport

Propylene glycol and dipropylene glycol are aliphatic trihydroxy chemicals that do not contain any hydrolyzable hydrogen. For this reason, the Agency granted a waiver from the aquatic hydrolysis study. However, the Agency has relied on data and fate properties of propylene glycol and dipropylene glycol obtained from published literature to assess environmental health risks.

These data suggest that propylene glycol and dipropylene glycol are miscible in water, mobile in soils, low absorptivity to soil, and stable to abiotic hydrolytic degradation as well as soil and aquatic photolysis. In aerobic soils, propylene glycol degrades to CO_2 in 4 days, whereas biodegradation of dipropylene glycol may be a slower process according to biological screening tests. However, this process may still be an important mechanism for removal of dipropylene glycol from aerobic soil. The low KOW indicates that propylene glycol and dipropylene glycol are not likely to bioaccumulate in aquatic organisms. With a vapor pressure of 0.129 mm Hg at 25 ^{o}C, propylene glycol and dipropylene glycol exist almost entirely in the vapor phase in the atmosphere and degrade rapidly (half-life approximately 13-32 hours) by reaction with photochemically produced hydroxyl radicals. Therefore, the presence of propylene glycol and dipropylene glycol in the environment, including the atmosphere, do not pose a concern.

2. Ecological Risk

a. Toxicity (Hazard) Assessment

As a result of the Phase IV review of propylene glycol and dipropylene glycol for reregistration under FIFRA, ecological effects data requirements were waived due to its high volatility, known low toxicity, and available data. Data obtained from published studies provide additional confirmation of the low toxicity of the compound to fish and aquatic invertebrates (Table 4). As mentioned earlier in this document, no toxicological endpoints were selected for risk assessment based on the available mammalian database.

Table 4. Ecotoxicity of Propylene Glycol and Dipropylene 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

Species	Percent Active Ingredient	Test Type	Toxicity	Reference
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 propylene glycol and dipropylene glycol due to the low likelihood of exposure. The very low toxicity of the compound to aquatic organisms, as indicated by the high LC_{50} values in the table above, further supports the unlikelihood of adverse effects to fish and aquatic invertebrates.

b. Risk to Listed Species

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 ensure 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 propylene glycol and dipropylene glycol, the Agency expects no effects to listed species or critical habitats 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 propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 ingredients propylene glycol and dipropylene glycol. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol containing products are eligible for reregistration. Appendix A summarizes the uses of propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol, and lists the submitted studies that the Agency found acceptable.

B. Comments and Responses

Supporting documents for propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol, the Agency will implement a 60-day 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 propylene glycol and dipropylene glycol. This conclusion is based on the results of toxicity testing of propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol. This conclusion is based on the results of toxicity testing of propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol.

Because no toxicological endpoints were identified for propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from propylene glycol and dipropylene 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 propylene glycol and dipropylene 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, propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 propylene glycol and dipropylene 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 Exemptions and Summary

Propylene glycol and dipropylene glycol are exempted from the requirement of a tolerance when used as a diluent (solvent, cosolvent). The following tolerance exemptions for propylene glycol and dipropylene glycol are listed in 40 CFR 180.910 [formerly 180.1001(c)] and only for propylene glycol in 180.930 [formerly 180.1001 (e)]:

> 180.910. Propylene glycol and dipropylene glycol are exempted from the requirement of a tolerance when used as a diluent (solvent, cosolvent) in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations when applied to growing crops or to raw agricultural commodities after harvest.
>
> 180.930. Propylene glycol is exempted from the requirement of a tolerance when used as a defoaming agent (solvent, cosolvent) in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

In addition to the above, propylene glycol is approved by the Food and Drug Administration (FDA) as a preservative in food products as listed in 21 CFR, Part 184-Direct Food Substances Affirmed as Generally Recognized as Safe (GRAS):

> 184.1666(d). The ingredient is used in foods at levels not to exceed current good manufacturing practice in accordance with Sec. 184.1(b)(1). Current good manufacturing practice results in maximum levels, as served, of 5 percent for alcoholic beverages, as defined in Sec. 170.3(n)(2) of this chapter; 24 percent for confections and frostings as defined in Sec. 170.3(n)(9) of this chapter; 2.5 percent for frozen dairy products as defined in Sec. 170.3(n)(20) of this chapter; 97 percent for seasonings and flavorings as defined in Sec. 170.3(n)(26) of this chapter; 5 percent for nuts and nut products as defined in Sec. 170.3(n)(32) of this chapter; and 2.0 percent for all other food categories.

a. Codex Harmonization

Currently there are no Codex MRLs established for propylene glycol and dipropylene glycol.

D. Regulatory Rationale

The Agency has determined propylene glycol and dipropylene glycol are eligible for reregistration. Based on the available data, the Agency has concluded that propylene glycol and dipropylene glycol exhibit low toxicity and exposure to propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol, the Agency expects no effects to listed species or critical habitats and therefore makes a "No Effect" determination for this chemical.

b. General Risk Mitigation

Propylene glycol and dipropylene glycol end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing propylene glycol and dipropylene 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 propylene glycol and dipropylene glycol are eligible for reregistration. No additional generic data are required at this time to support this decision.

For end use products containing the active ingredient propylene glycol and dipropylene 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)
Marshall Swindell
US EPA (7504P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI)
Marshall Swindell
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing-Use Products

There are no currently registered propylene glycol and dipropylene glycol manufacturing-use products.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of propylene glycol and dipropylene 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 (propylene glycol and dipropylene, 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. A list of product-specific efficacy data requirements is listed in Table 5 below.

Table 5. Product-specific Efficacy Data Requirements

Guideline Number	Study Title
810.2100 (c,d,e)	Products for use on hard surfaces – AOAC use dilution/germicidal spray/carrier.
810.2100 (g)	Products for use on hard surfaces – virucidal activity method.
810.2100 (f)	Products for use on hard surfaces – fungicidal test.
810.2100 (l)	Products for use on hard surfaces – hard inanimate surface non-food.
810.2400 (b,l)	Chemical analysis.
830.7050	UV/Visible absorption.

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
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

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
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

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
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

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
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.

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
	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 µl 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 µl 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.

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
	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

Use Site	Formulation	Application Rate (Range)	No. of Applications	Use Limitations
	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 µl 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 µl 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 µl 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 µl 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 µl 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 µl 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 µl 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 µl 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 propylene glycol and dipropylene glycol. These requirements apply to propylene glycol and dipropylene glycol 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.

   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.

3.
(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
Materials preservatives
(8) Industrial processes and water systems
Antifouling coatings
Wood preservatives
Swimming pools
(7) Aquatic areas

(9) 4. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement,
(10) this column will identify each study by a "Master Record Identification (MRID) number. The listed studies are considered
(11) "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of
(12) 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	43178601, 43179501
830.1600 830.1620 830.1650	61-2A	Starting Materials and Manufacturing Process	2,3,4,5	43178601, 43179501
830.1670	61-2B	Formation of Impurities	2,3,4,5	43178601, 43179501
830.1700	62-1	Preliminary Analysis	2,3,4,5	43178601, 43179502, 43858501
830.1750	62-2	Certification of Limits	2,3,4,5	43178601, 43179502
830.1800	62-3	Analytical Method	2,3,4,5	43178602, 43179502
830.6302	63-2	Color	2,3,4,5	43178603, 43179503
830.6303	63-3	Physical State	2,3,4,5	43178603, 43179503
830.6304	63-4	Odor	2,3,4,5	43178603, 43179503
830.7200	63-5	Melting Point	2,3,4,5	Not required
830.7220	63-6	Boiling Point	2,3,4,5	43178603
830.7300	63-7	Density	2,3,4,5	43178603
830.7840 830.7860	63-8	Solubility	2,3,4,5	43178603, 43179503
830.7950	63-9	Vapor Pressure	2,3,4,5	43178603, 43179503
830.7370	63-10	Dissociation Constant in Water	2,3,4,5	Not required

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	2,3,4,5	43178603, 43179503
830.7000	63-12	pH	2,3,4,5	43178603, 43179503
830.6313	63-13	Stability	2,3,4,5	43178603, 43179503
830.6314	63-14	Oxidizing/Reducing Action	2,3,4,5	Not required
830.6315	63-15	Flammability	2,3,4,5	43178603, 43179503
830.6316	63-16	Explodability	2,3,4,5	Not required
830.6317	63-17	Storage Stability	2,3,4,5	43178603, 43179503
830.7100	63-18	Viscosity	2,3,4,5	43178603, 43179503
830.6319	63-19	Miscibility	2,3,4,5	43178603, 43179503
830.6320	63-20	Corrosion Characteristics	2,3,4,5	43178603, 43179503
830.6321	63-21	Dielectric breakdown voltage	2,3,4,5	Not required
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test - Quail/duck	2,3,4,5	43762301, 43888002 43760807
850.1075	72-1 c	Fish Acute Toxicity - Rainbow Trout	2,3,4,5	Open literature
850.1075	72-1 c	Fish Acute Toxicity - Fathead Minnow	2,3,4,5	Open Literature
850.1010	72-2 a	Acute Aquatic Invertebrate Toxicity	2,3,4,5	43762302, 43888003, 43760808

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1300	72-4 a	Fish Early Life Stage	2,3,4,5	Not required
850.1400	72-4 b	Aquatic Invertebrate Life Cycle	2,3,4,5	Not required
Non-guideline	Non-guideline	Acute Aquatic Invertebrate Toxicity - Waterflea *(Ceriodaphnia dubia)*	N/A	Not required; Open literature
Non-guideline	Non-guideline	Acute Aquatic Invertebrate Toxicity - Waterflea *(Daphnia magna)*	N/A	Not required; Open literature
Non-guideline	Non-Guideline	Acute Aquatic Invertebrate Toxicity – Brine Shrimp *(Artemia salina)*	N/A	Not required; Open literature
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	2,3,4,5	43760801, Open literature
870.1200	81-2	Acute Dermal - Rabbit	2,3,4,5	43760802, Open literature
870.1300	81-3	Acute Inhalation – Rat	2,3,4,5	43760803, Open literature
870.2400	81-4	Acute Eye Irritation - Rabbit	2,3,4,5	43760804, Open literature
870.2500	81-5	Acute Skin Irritation - Rabbit	2,3,4,5	43760805, Open literature
870.2600	81-6	Dermal Sensitization	2,3,4,5	43760806, Open literature
870.3100	82-1a	Subchronic (Oral) Toxicity –Rodent	2,3,4,5	46892504, 46892208, Open literature
870.3465	82-4	90-Day (Inhalation) Subchronic Toxicity	2,3,4,5	46892103
870.4100	83-1a	Chronic (Oral) Toxicity - Rodent	2,3,4,5	46892509, Open literature
870.4100	83-1a	Chronic (Inhalation) Toxicity - Rodent	2,3,4,5	Open literature

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.4300	83-5	Combined Chronic (Oral) Toxicity/Carcinogenicity - Rodent	2,3,4,5	46892504,46892101, Open literature
870.4300	83-5	Combined Chronic (Dermal) Toxicity/Carcinogenicity - Rodent	2,3,4,5	46892301
870.3700	83-3a	Prenatal Developmental Toxicity - Rodent	2,3,4,5	46892202, 46892203, 46892206, 46892207, 46892508, Open literature
870.3700	83-3b	Prenatal Developmental Toxicity – Non Rodent	2,3,4,5	46892205, Open literature
870.3800	83-4	Reproduction and Fertility Effects - Rat	2,3,4,5	46892204, Open literature
870.5100	84-2	Bacterial Reverse GeneMutation Assay Test	2,3,4,5	Open literature
870.5300	84-2	In Vitro Mammalian Cell Gene Mutation Test	2,3,4,5	Open literature
870.5375	84-2	Cytogenetics: In Vitro Mammalian Chromosome Aberration Test	2,3,4,5	Open Literature
870.5395	84-2	Cytogenetics: In Vivo Mouse Erythrocyte Micronucleus Assay	2,3,4,5	Open Literature
870.5450	84-2	Other Mechanisms: Rodent Dominant Lethal Assay	2,3,4,5	46892506, Open literature
870.6200	81-8	Neurotoxicity Screening Battery	2,3,4,5	Open literature
870.7485	85-1	Metabolism and Pharmocokinetics - Rodent	2,3,4,5	46892202, 46892201, 46893505, Open literature
870.7600	85-2	Dermal Penetration - Rodent	2,3,4,5	46892301
ENVIRONMENTAL FATE				

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
835.2120	161-1	Hydrolysis of Parent and Degradates	2,3,4,5	Not required

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 propylene glycol and dipropylene 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:

1. **Propylene Glycol/Dipropylene Glycol** - Report of the Antimicrobials Division Toxicology Endpoint Selection Committee. (Memorandum: T. McMahon, Ph.D., Chair, July 20, 2004.

2. ***PROPYLENEGLYCOL/DIPROPYLENE GLYCOL:*** Revised Toxicology Chapter in Support of issuance of the Reregistration Eligibility Decision (RED) Document. PC Code for Propylene Glycol: 068603. PC Code for Dipropylene Glycol: 068604. CAS Registry Number for Propylene Glycol: 57-55-6: CAS Registry Number for Dipropylene Glycol: 25265-71-8. Reregistration Case Number: 3126, DP #: 327061. (Memorandum: M. Centra, Pharmacologist, February 5, 2007).

3. Data Evaluation Records (DER) for the Product Chemistry of Propylene Glycol. (Memorandum: N. Shamim, Chemist, December 10, 2003).

4. Data Evaluation Records (DER) for the Product Chemistry of Dipropylene Glycol. (Memorandum: N. Shamim, Chemist, December 10, 2003).

5. Science Chapter: Revised Environmental Fate Studies and Environmental Fate Assessment of Propylene Glycol (Memorandum: N. Shamim, Chemist, February 5, 2007).

6. Science Chapter: Revised Environmental Fate Studies and Environmental Fate Assessment of Dipropylene Glycol (Memorandum: N. Shamim, Chemist, February 5, 2007).

7. PROPYLENE GLYCOL AND DIPROPYLENE GLYCOL: Estimated Drinking Water Concentrations (Memorandum: N. Shamim, Chemist, July 2, 2004).

8. AD's Revised Occupational and Residential Exposure Chapter for the Propylene and Dipropylene Glycol Reregistration Eligibility Decision (RED) Document. Case No. 3126. PC Codes 068603, 068604. (Memorandum: T. Leighton, Environmental Scientist, February 5, 2007).

9. Propylene/Dipropylene Glycol Revised Ecological Hazard and Environmental Risk Characterization Chapter for the Reregistration Eligibility Decision (RED) Document, Case 3126. (Memorandum: K. Montague, M.S., Biologist, February 14, 2006).

10. ***PROPYLENE GLYCOL/DIPROPYLENE GLYCOL:*** AD's Risk Assessment for Issuance of the Reregistration Eligibility Decision (RED) Document. Reregistration Case No.: 3126. PC Codes: 068603, 068604. CAS Registry No.: Propylene Glycol, 57-55-6; Dipropylene Glycol, 25265-71-8. (Memorandum: M. Centra, Pharmacologist/Risk Assessor, February 5, 2007).

Appendix D: Bibliography Citations

MRID Number	Citation
43176202	Davis, K. (1994). Product Chemistry Data of Propylene Glycol. Unpublished report prepared by RegWest Company, Greeley, CO. 21 p. Guideline Series 62/OPPTS 830.1760 and 830.1800
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43178601	Davis, K. (1994). Product Chemistry Data of Propylene Glycol. Unpublished report prepared by RegWest Company, Greeley, CO. 11 p. Guideline Series 61/OPPTS 830.1550, 830.1600, 830.1620, 830.1650,830.1670 and 830.1700.
43178602	Davis, K. (1994). Product Chemistry Data of Propylene Glycol:Lab Project Number:PG62. Unpublished Study prepared by RegWest Co. 21 p.
43178603	Davis, K. (1994). Physical and Chemical Characteristics of Propylene Glycol:Lab Project Number:PG63. Unpublished Study Prepared RegWest Co. 76 p.
43179501	Davis, K. (1994). Product Chemistry Data of Dipropylene Glycol. Unpublished report prepared by RegWest Company, Greeley, CO. 11 p. Guideline Series 61/OPPTS 830.1550, 830.1600, 830.1620, 830.1650 and 830.1670.
43179502	Davis, K. (1994). Product Chemistry Data of Dipropylene Glycol. Unpublished report prepared by RegWest Company, Greeley, CO. 21 p. Guideline Series 62/OPPTS 830.1700, 830.1760 and 830.1800.
43179503	Davis, K. (1994). Physical and Chemical Characteristics of Dipropylene Glycol: Lab Project Number: DPG63. Unpublished Study prepared by RegWest Co. 68 p.

43760801 Robbins, G. (1995) Dipropylene Glycol: Acute Oral Toxicity in Rats: Lab Project Number: A3435. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 21 p. The CSPA Glycols Joint Venture Project ID A3435. Work Assignment No. 2-28A.

43760802 Robbins, G. (1995) Dipropylene Glycol: Acute Dermal Toxicity on Rabbits: Lab Project Number: B3435. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 23 p. The CSPA Glycols Joint Venture Project ID B3435. Work Assignment No. 2-28B.

43760803 Robbins, G. (1995) Dipropylene Glycol: Acute Inhalation Study in Rats: Lab Project Number: C3435. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 35 p. The CSPA Glycols Joint Venture Project ID C3435. Work Assignment No. 2-28C.

43760804 Robbins, G. (1995) Dipropylene Glycol: Primary Eye Irritation in Rabbits: Lab Project Number: D3435. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 22 p. The CSPA Glycols Joint Venture Project ID D3435. Work Assignment No. 2-28D.

43760805 Robbins, G. (1995) Dipropylene Glycol: Primary Dermal Irritation on Rabbits: Lab Project Number: E3435. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 18 p. The CSPA Glycols Joint Venture Project ID E3435. Work Assignment No. 2-28E.

43760806 Robbins, G. (1995) Dipropylene Glycol: Dermal Sensitization (Buehler) on Guinea Pigs: Lab Project Number: F3435. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 45 p. The CSPA Glycols Joint Venture Project ID F3435. Work Assignment No. 2-28F.

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Supporting Documentation

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Appendix E: Generic Data Call-In

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

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 Propylene glycol and Dipropylene 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 propylene glycol and dipropylene glycol, the Agency has batched products which can be considered similar in terms of acute toxicity. (The PC Code of propylene glycol is 068603; the CAS Registry Number is 57-55-6; The PC Code of propylene glycol is 068604; the CAS Registry Number is 25265-71-8). 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. 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. 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. Registrants may not support their product using data conducted on a product from a different batch, unless this batching appendix specifically states so. 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. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In (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 Propylene glycol and dipropylene Glycol.

Table 1.

Batch	Registration Number	Percent Active Ingredient
1	51838-1	Propylene glycol and dipropylene Glycol ... 4.4% Propylene Glycol ... 4.4%
	51838-2	Propylene glycol and dipropylene Glycol ... 4.4% Propylene Glycol ... 4.4%
2	4822-293	Propylene glycol and dipropylene Glycol ... 6.0%
	4822-531	Propylene glycol and dipropylene 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 Propylene glycol and dipropylene Glycol as an Active Ingredient

Registration Number	Percent Active Ingredient
9444-19	Propylene glycol and dipropylene Glycol ... 6.000% Dipropylene Glycol ... 4.000% n-Alkyl dimethyl benzyl ammonium chloride ... 0.20%
9444-136	Propylene glycol and dipropylene Glycol ... 9.15% Dipropylene Glycol ... 3.43% n-Alkyl dimethyl benzyl ammonium chloride ... 0.17%
10807-24	Propylene glycol and dipropylene Glycol ... 4.5% Propylene Glycol ... 3.0% n-Alkyl dimethyl benzyl ammonium chloride ... 0.10%
10807-37	Propylene glycol and dipropylene 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	Propylene glycol and dipropylene Glycol ... 7.7% Propylene Glycol ... 5.13% n-Alkyl dimethyl benzyl ammonium chloride ... 0.17%
11715-20	Propylene glycol and dipropylene Glycol ... 0.10% Propylene Glycol ... 0.10% Pyrethrins ... 0.09% Piperonyl butoxide ... 0.18% n-Octyl bicycloheptene dicarboximide ... 0.30%
44446-20	Propylene glycol and dipropylene 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 Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC 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.