US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Polypropylene Glycol

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Agency

Prevention, Pesticides
And Toxic Substances
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Reregistration Eligibility Decision for Polypropylene Glycol

Reregistration Eligibility Decision (RED) Document for Polypropylene Glycol

List C

Case No. 3123

Approved by: _____
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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
G	Granular Formulation
GLN	Guideline Number
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing

SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Summary

The Environmental Protection Agency (hereafter referred to as "EPA" or "the Agency") has evaluated the risks from the supported uses of polypropylene glycol and has determined that no unreasonable adverse effects will result from exposure to butoxypolypropylene glycol (BPG), the only active ingredient in the polypropylene glycol case with registered products. The Agency has determined that the products containing polypropylene glycol are eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made.

BPG is a repellant that is used to control flying and crawling insects. BPG was first registered for use in 1960, and can be applied to animals such as pets or horses directly, or to areas where animals live, like animal housing, bedding, or other areas animals may occupy. Approximately 300,000 pounds of BPG are sold annually. There are no food uses, and no uses on animals intended for slaughter.

The Agency conducted a human health risk assessment to estimate the potential risk from BPG in residential settings. Dietary (drinking water) exposure, residential handler exposure, and post-application residential exposure were all assessed. In addition, those activities that could lead to multiple exposures were aggregated. All risks assessed for residential exposure were below the Agency's level of concern.

The Agency also conducted a risk assessment on the occupational uses of BPG, including handlers that mix, load, and apply BPG in various ways. Two scenarios for handlers using liquid concentrate and impregnated wipe products presented potential risk to handlers when only baseline personal protection equipment (PPE) was assumed. The addition of chemical-resistant gloves for both scenarios will address these risks, and results in risk estimates below the Agency's level of concern. Therefore, to address potential dermal risk concerns for handlers using liquid concentrate product or impregnated wipe products, chemical resistant gloves are required to be eligible for reregistration.

An ecological effects risk assessment was also conducted for BPG. Due to the limited potential exposure pathways that BPG could enter the environment, the assumptions used in the ecological risk assessment are considered to be conservative. There were some quantitative risk calculation exceedances for some non-target species based on these conservative assumptions, but there is sufficient information to conclude that the risks are not of concern.

A summary of the risk mitigation measures that are required for BPG is included in Table 1.

Table 1: Summary of Risk Mitigation Measures	
Risk of Concern	**Mitigation Measure**
Dermal risk to handlers mixing, loading, and applying liquid concentrate products	Require chemical resistant gloves for mixers, loaders, and applicators using liquid concentrates.
Dermal risk to handlers applying impregnated wipe products	Require chemical resistant gloves for applicators using impregnated wipes.

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 Food Quality Protection Act of 1996 (FQPA) and the Pesticide Registration Improvement Act of 2003 (PRIA) to set time frames for the issuance of Reregistration Eligibility Decisions. FIFRA calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the U.S. Environmental Protection 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 risks arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the EPA's reregistration and risk management decision for the registered uses of polypropylene glycol. There are two active ingredients in the polypropylene glycol case; however, one of these active ingredients has no active registered products. This chemical, poly(oxy(methyl-1,2-ethanediyl)), alpha-hydro-omega-hydroxy (PC 068602), has no active registered products, is not being supported, and is not addressed in this reregistration decision. Butoxypolypropylene glycol (PC 011901) is the only active ingredient in the case with active products.

The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of polypropylene glycol are eligible for reregistration provided the mitigation and labeling changes outlined in this RED are implemented.

II. Chemical Overview

A. Regulatory History

There are 2 active ingredients in reregistration case 3123 for polypropylene glycol as listed in Table 2. This RED evaluates the only active ingredient in this case with currently registered products; therefore, only butoxypolypropylene glycol (BPG), PC Code 011901 was assessed. The other active ingredient in this case has no product registrations and is not being supported for reregistration. This active ingredient would be evaluated only if and when new registration applications were to be submitted for new products.

Table 2: Ingredients in the Polypropylene Glycol Chemical Case (3123)

PC Code	Chemical Name	CAS Number	Status
068602	Poly(oxy(methyl-1,2-ethanediyl)), alpha-hydro-omega-hydroxy	25322-69-4	Last pesticide product cancelled October 10, 1989. Not supported for reregistration.
011901	Alpha-Butyl-omega-Hydroxypoly(oxy(methyl-1,2-ethanediyl) [BPG]	9003-13-8	57 active products as of September, 2007. Being supported for reregistration.

BPG was first registered by FMC in 1960. Bayer Environmental Science (BES) is currently the sole technical registrant.

B. Chemical Identification

The nomenclature of BPG is in Table 3, and the physicochemical properties are listed in Table 4.

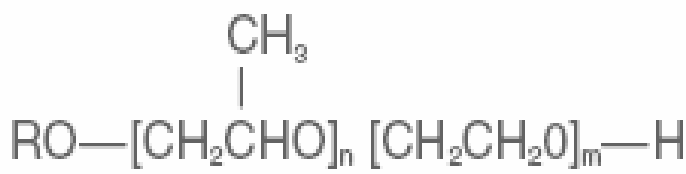
Table 3: Butoxypolypropylene Glycol (BPG) Nomenclature	
Chemical Structure	 R = CH_3 CH_2 CH_2 CH_2 n = 18 (average) m = 0
Chemical Name	alpha-butyl-omega-hydroxy-poly-oxy(methyl-1,2-ethanediyl)
IUPAC Name	1-(1-butoxypropan-2-yloxy)propan-2-ol
Common name	Butoxypolypropylene Glycol (BPG)
CAS Registry Number	9003-13-8
Molecular Formula	$(C_3H_6O)_nC_4H_{10}O$
Chemical Class	Repellent

Table 4: Physicochemical Properties of BPG

Parameter	Value	Reference
Molecular Weight	1119.58	Ecological Risk Assessment, D338965, 8/21/07
Melting point/range	None; turns to a glass at -43º C	MRID 42541403
Density	0.989 at 20 º C	MRID 42541403
Boiling point	None; BPG starts to decompose at ~ 250 °C	MRID 42541403
Solvent solubility (temperature not specified)	Soluble in acetone, n-butanol, cyclohexane, butyl ether, ethylene dichloride, heptane, isopropanol, methanol, petroleum ether, toluene. Insoluble in diethylene glycol, ethylene glycol, glycerol, propylene glycol, water.	MRID 42541403
Vapor pressure (25°C)	2.81×10^{-27} mm Hg	Ecological Risk Assessment, D338966
Dissociation constant, pKa	Not known. BPG is essentially a high molecular weight alcohol. The alcohol portion should have a dissociation constant similar to other secondary alcohols.	MRID 42541403
Octanol/water partition coefficient, $\log P_{OW}$ (25°C)	Not known. BPG will exist primarily in the octanol phase.	MRID 42541403
UV/visible absorption spectrum	Not available	

C. BPG Use Profile

Type of Pesticide: Repellent

Summary of Use: Insect control for companion and equine animals, applied both to animals directly (on-animal), and to areas where animals live (off-animal). The on-animal products are sold for equine and companion animals. The off-animal products can be applied as a space spray in animal housings and other areas where animals live. There are no food uses, and no uses on animals intended for slaughter.

BPG is included in EPA's approved Inerts List 3, "Inerts of Unknown Toxicity." The Agency continues to evaluate substances on List 3 and, as additional information becomes available, determine if reclassification is appropriate.

BPG also has an FDA-regulated pharmaceutical use as a diluent in defoamers used in the pulping of lignocellulosic materials that will be used to make food-contact paper and paperboard. Use of BPG may not exceed 8 grams per metric ton of dry pulp (0.0008%).

BPG is also a manufacturing ingredient marketed as UCON™ Fluid LB-250. It is sold by DOW Chemical Company to formulators who use it as a sole lubricant or mix it with other fluids as a base to their own lubricant. DOW's UCON™ base stocks are polyalkylene glycols (PAGs), which are polymers of ethylene oxide and propylene oxide.

Target Organisms : Deer flies, face flies, gnats, horn flies, horse flies, house flies, mosquitoes, stable flies, chiggers, lice, ticks, army worm, bot flies, wasps, fleas, biting flies, chiggers (bed bugs), ants, and roaches.

Mode of Action: Repel biting insects that are a nuisance to animals listed above. The mode of action is not known.

Use Classification: General Use

Formulation Type: Emulsifiable concentrate (EC) and a variety of ready-to-use (RTU) formulations. BPG is never used as the sole active ingredient in a product, but is often formulated with pyrethrins, piperonyl butoxide, and pyrethroids.

Application Methods: Aerosol sprays, emulsifiable and soluble concentrate, ready-to-use liquids (trigger spray, roll-on, gels/ointments), solids (repellent stick), and impregnated materials (wipes).

Application Rates: Rates vary depending upon the exposure scenario and the number of animals or the use-site treated.

Usage: Approximately 300,000 pounds of BPG are sold annually.

III. Risk Assessment Summary

The following is a summary of EPA's human health and ecological risk findings and conclusions for BPG, as presented fully in the Health Effects Division document, *Butoxypolypropylene Glycol: Revised HED Chapter of the Reregistration Eligibility Decision Document,* (Lloyd, September 2007), and the Environmental Fate and Effects Division documents, *EFED RED Chapter for Butoxy Polypropyleneglycol*, (Odenkirchen, September 2007) and *Drinking Water Assessment for the Reregistration Eligibility Document for butoxypolypropylene glycol*, (Khan, August 2007).

A. Human Health Risk Assessment

The Agency has conducted a human health risk assessment for BPG for the purposes of making a reregistration eligibility decision. The Agency evaluated the toxicology, product and residue chemistry, and occupational/residential exposure studies submitted and determined that the data are adequate to support a reregistration decision. However, a 28-day oral toxicity study (OPPTS 870.3050) is required to more accurately assess the potential risks resulting from repeated oral exposure and to confirm the determination presented here. A summary of the human health risk assessment findings and conclusions are provided below.

1. Toxicity

BPG is not acutely toxic via the oral or dermal route of exposure, and it is a minor eye and skin irritant (Category III). Acute inhalation data on technical grade BPG are not available but a formulation of BPG (Pyrenone®7.5-0.75 Stabilene®53% E.C.; end use product) is not acutely toxic via the inhalation route of exposure. See Table 5 below.

Table 5: Acute Toxicity Profile - Butoxypolypropylene Glycol Technical

Guideline No.	Study Type	MRID #	Results	Toxicity Category
870.1100	Acute Oral -rat	41884504	LD50 >5000 mg/kg	IV
870.1200	Acute Dermal - rabbit	41884503	LD50 > 2000 mg/kg	III

Table 5: Acute Toxicity Profile - Butoxypolypropylene Glycol Technical				
Guideline No.	Study Type	MRID #	Results	Toxicity Category
870.1300	Acute Inhalation – Rat	00071332	LC50 > 2.62 mg/L	IV [a]
870.2400	Primary Eye Irritation - Rabbit	41884501	A minor eye irritant	III
870.2500	Primary Skin Irritation - Rabbit	41884502	A minor dermal irritant	III

[a] Tested material was a BPG formulation (EPA Reg # 432-1060) which consisted of BPG (53%), piperonyl butoxide (7.5%) and pyrethrins (0.75%).

The toxicity database for repeat exposures to BPG is limited to two dermal rat studies. In the 90-day rat dermal toxicity study, the toxicity effects of decreased body-weight gain and food efficiency and alterations in hematological parameters, were observed at the systemic LOAEL of 4000 mg/kg/day. Clinical signs of skin irritation, including scaling and cracking, were observed at the limit dose of 1000 mg/kg/day. In the dermal developmental toxicity study in rats, decreased body-weight gain was observed at a dose level greater than the limit dose of 1000 mg/kg/day. No developmental toxicity was observed at the highest dose tested (4000 mg/kg/day).

Since there was no appropriate oral study with repeat dosing available, a material balance study in rats was used to calculate the oral point of departure based on the dermal endpoint selected for BPG. To convert a dermal NOAEL to an oral NOAEL, the Agency used a material balance study that showed 12% of BPG was absorbed dermally. Converting the dermal NOAEL of 1000 mg/kg/day to the oral equivalent produces a NOAEL of 120 mg/kg/day [1,000 x (0.12) = 120 mg/kg/day].

Given that the BPG database also does not contain an acceptable route-specific inhalation study, the systemic inhalation toxicity is assumed to be equivalent to the oral NOAEL of 120 mg/kg/day.

Carcinogenicity

Mutagenicity tests, both in vivo and in vitro, were negative for BPG. There are no carcinogens that are structurally related to BPG based on a structure-activity relationship (SAR) analysis. Based on the current use pattern and registered non-food uses for BPG, a carcinogenicity study is not required.

A point of departure is the data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. Table 6 contains selected points of departure for the human risk assessments.

Table 6: Summary of Toxicological Doses and Endpoints for BPG Use in Human Risk Assessments				
Exposure Scenario	**Point of Departure (PO D)**	**Uncertainty Factors**	**RfD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (general population including infants and children)	NOAEL of 120 mg/kg/day Oral equivalent NOAEL= 120 mg/kg/day (a)	UF_A=10X UF_H=10X	aRfD = 1.2 mg/kg/day	No appropriate endpoint attributable to a single exposure (dose) was identified for an acute dietary (drinking water) endpoint. Therefore, the Agency used the short-term incidental oral endpoint (NOAEL of 120 mg/kg/day).
Chronic Dietary (all populations)	NOAEL= 1000 mg/kg/day Oral equivalent NOAEL= 120 mg/kg/day (a)	UF_A=10X UF_H=10X	cRfD = 1.2 mg/kg/day	90- day dermal toxicity study in rats LOAEL= 4000 mg/kg/day based on reduced body weight gain and changes in hematological parameters.
Incidental Oral Short- and Intermediate-Terms	NOAEL= 1000 mg/kg/day Oral equivalent NOAEL= 120 mg/kg/day (a)	UF_A=10X UF_H=10X	Residential and Occupational LOC for MOE= 100	90- day dermal toxicity study in rats; Same as for chronic reference dose (cRfD)
Dermal Short- and Intermediate-Terms	NOAEL= 1000 mg/kg/day			
Inhalation Short- and Intermediate-Terms	Oral equivalent NOAEL= 120 mg/kg/day (b)			
Cancer Classification	BPG is non-mutagenic in vivo and in vitro. There are no carcinogens that are structurally related to BPG.			

(a) Since a dermal study was selected, 12% dermal bioavailability was used to calculate oral equivalents. To convert dermal NOAEL to oral NOAEL multiply dermal NOAEL by 0.12. That is, to convert from dermal NOAEL of 1000 mg/kg/day, the oral equivalent NOAEL = (1,000) x (0.12) = 120 mg/kg/day.

(b) The systemic inhalation toxicity is assumed to be equivalent to the oral systemic toxicity for the purposes of this assessment; no inhalation absorption data are available.

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

2. Dietary Risk (Drinking Water Only)

There are no registered food or feed uses for BPG; therefore, a food-related dietary risk assessment is not necessary and has not been conducted. However, since BPG products are used outdoors in animal quarters/stables and for outdoor animal applications to horses and other animals, the risk assessment considered drinking water exposures from surface water sources.

Acute and chronic drinking water risk assessments were performed using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. An Estimated Drinking Water Concentration (EDWC) point estimate value was calculated with EPISUITE (v.3.20) using the limit of solubility for BPG of 0.000193 mg/L. Since the use patterns of BPG are limited to animal applications and indoor areas, the Agency did not use the typical agricultural modeling approach with PRZM/EXAMS.

The acute and chronic dietary assessment incorporates both exposure to and dietary toxicity of BPG, although the Agency believes that chronic exposure is unlikely from current use patterns. No appropriate endpoint attributable to a single exposure (dose) was identified for an acute dietary (drinking water) endpoint. Therefore, the Agency used a material balance study to extrapolate the dermal NOAEL of 1000 mg/kg/day from the 90-day dermal rat study (sub-chronic exposure) to the oral equivalent producing a NOAEL of 120 mg/kg/day [1,000 x (0.12) = 120 mg/kg/day]. This is a conservative surrogate for the acute dietary endpoint because the endpoint was selected from the subchronic toxicity study rather than an acute toxicity study.

The chronic dietary endpoint was based on the same NOAEL from the 90-day dermal toxicity study in rats. This is a conservative surrogate for the chronic dietary endpoint because the toxicity (reduced body-weight gain and food efficiency and alterations in hematology parameters) occurred throughout the study and the body weight effects lessened with time of exposure.

An uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variation) was applied to the NOAEL. The acute Reference Dose (aRfD) is the dose an individual could be exposed to in one day and no adverse health effects would be expected. The chronic Reference Dose (cRfD) is the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected. The aRfD and cRfD were both calculated as 120 mg/kg/day ÷ 100 = 1.2 mg/kg/day. Risk is expressed as a percentage of the aRfD or cRfD. A risk estimate less than 100% of the aRfD or cRfD does not exceed the Agency's level of concern.

Dietary risk estimates were calculated for the general U.S. population and various population subgroups as shown in Table 7. BPG acute and chronic dietary (drinking water) exposure estimates for the U.S. population (<0.1% of the aRfD and cRfD) and for

the most highly exposed population subgroups, all infants (<0.1% of the aRfD and cRfD), are below the Agency's level of concern.

Table 7: Summary of Drinking Water Exposure and Risk for BPG

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aRfD*	Dietary Exposure (mg/kg/day)	% cRfD*
General U.S. Population	0.000005	<0.1%	0.000002	<0.1%
All Infants (< 1 year old)	0.000034	<0.1%	0.000012	<0.1%

* RfD = reference dose; a = acute, c = chronic

3. Residential Exposure and Risk

For more detail on the residential exposure and risk assessment, see the *Butoxypolypropylene Glycol: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision*, (Lloyd, August 2007).

Non-cancer risk estimates are expressed as a margin of exposure (MOE) which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is 100X which includes 10X for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10X for intraspecies variation (to account for differences between humans). For BPG, MOEs greater than 100 for incidental oral exposure, inhalation exposure, and dermal exposure do not exceed the Agency's level of concern.

a. Residential Handler Exposure and Risk

BPG can be used in the residential setting (on-animals and their bedding). Given that BPG is designed to repel biting insects (flies, gnats, mosquitoes), short- and intermediate-term (1-6 months) exposures are assessed due to the occasional nature of applications by homeowners. The Agency assessed inhalation and dermal exposure for the following residential handler scenarios:

<u>Mixer/Loader/Applicators:</u>

1) Liquid: Low Pressure Handwand Sprayers;
2) Liquid: Sponge Applications to Horses;
3) Ready-To-Use Liquids: Pour-on;
4) Ready-To-Use Wipe Applications;
5) Ready-To-Use Trigger Pump Sprayer Applications;
6) Ready-To-Use Aerosol Cans to Outdoor Surfaces and Pets;

7) Applying Crack and Crevice Treatment with Aerosol Cans (inhalation exposure only was assessed for this scenario because no dermal exposure is expected).

All residential handler risk estimates are below the Agency's level of concern; all of the MOEs are greater than 100. MOEs for residential handlers range from about 300 to greater than 10,000.

b. Residential Post-Application Exposure and Risk

Residential post-application exposures could occur when bystanders, such as children, come in contact with BPG in areas where end-use products have recently been applied. Contact with treated pets and pet bedding are two common examples of post-application exposures.

The following scenarios were evaluated for post-application exposures to BPG:

1) Hand-to-mouth activity for toddlers on carpeted indoor surfaces (used as a surrogate for pet bedding) treated with BPG
2) Dermal exposure for toddlers and adults to carpeted indoor surfaces (surrogate for contact with pet bedding) treated with BPG
3) Dermal exposure for toddlers after exposure with BPG-treated pets (pet "hug" scenario)
4) Hand-to-mouth activity for toddlers after contact with BPG treated pets

No post application inhalation assessment has been conducted for aerosol product applications; the residential handler inhalation assessment is protective of post application inhalation risks because the exposures to handlers in those scenarios are expected to be significantly greater. There are no residential post-application risk estimates of concern to the Agency; all of the MOEs are greater than 100. MOEs for residential post-application risk range from 105 to 2,400. The MOE of 105 represents risk estimated for toddler dermal post-application exposure from treated pets. The residue levels which were used to calculate toddler exposure were determined using a 5 minute rubbing/petting technique that leads to concentrations of residue on the hands that would be expected to be higher than would result from a single contact with a treated pet.

Since common toxicity endpoints (reduced body weight gain/alterations of hematology parameters) were used to calculate dermal and inhalation risks for each exposure duration, the Agency calculated the combined risk from two of the BPG post-application exposure scenarios. These two scenarios could potentially expose toddlers through different routes of exposure to BPG simultaneously based on the nature of the use-pattern and the behavior of toddlers. The combined risks from dermal and oral exposure in (1) a pet "hug" scenario and (2) a pet bedding/quarters scenario do not present potential post-application risks of concern to toddlers (MOEs are 180 and 101 respectively). This toddler scenario is protective of the general population exposed.

4. Aggregate Risk

In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route (oral, dermal, and inhalation) and duration (short-, intermediate-, or long-term) of exposure. Acute, intermediate, and chronic aggregate risk assessments are not conducted based on the use patterns of BPG.

The Food and Drug Administration (FDA) has approved and regulates the use of BPG as a defoaming agent used in the manufacture of paper and paperboard. Any additional exposure from this use would likely be negligible. Therefore, non-pesticide uses of BPG have not been included in the aggregate risk assessment.

Infants and Children

For residential exposure, three children subpopulation groups were examined: all infants (<1 year) who showed the highest exposure to BPG in drinking water, and children 1-2 and 3-5 years old who might exhibit hand-to-mouth behaviors. Residential handler inhalation exposures were aggregated for adults (residential handlers) but infants and children are not likely to apply BPG products, or likely be exposed to BPG through the inhalation route for the same reason. The highest dermal and oral exposure contribution for children and infants is from the pet-hug scenario. The pet-hug scenario assumes a child embraces a family dog after the pet has been treated with a BPG product once per day. Conservative water exposure values were again included in the aggregate risk assessment. The aggregate MOEs for all infant and children populations are all 101, which is above an MOE of 100 and below EPA's level of concern.

Adult

The short-term aggregate risk assessment for adults combines handler and post-application scenarios. For residential aggregate risk, an application of liquids via sponge was used to estimate the dermal and inhalation exposure contribution of the aggregate risk because the scenario was demonstrated to have the highest exposure for both routes among the scenarios chosen. Adults do not exhibit the hand-to-mouth behaviors that infants and children do and no oral exposure is assumed for the adult population. Conservative water exposure values were used in the aggregate risk assessment as well. The aggregate MOE for adults is 315, which is above an MOE of 100 and below EPA's level of concern. Table 8 summarizes the short-term aggregate risk calculations.

Table 8: Summary of Short-Term Aggregate Risk Calculations						
Population	**Short-Term Scenarios**					
	LOC for Aggregate Risk	**MOE water** (exposure in mg/kg/day)	**MOE oral** (exposure in mg/kg/day)	**MOE dermal** (exposure in mg/kg/day)	**MOE inhalation** (exposure in mg/kg/day)	**Aggregate MOE (water and residential)[1]**
General population [adult]	100	60,000,000 (0.000002)	N/A	340 (2.9)	4,200 (0.029)	315
All infants <1 year old	100	10,000,000 (0.000012)	2,400 (0.051)	105 (9.48)	N/A	101
Children 1-2 years old	100	60,000,000 (0.000002)	2,400 (0.051)	105 (9.48)	N/A	101
Children 3-5 years old	100	60,000,000 (0.000002)	2,400 (0.051)	105 (9.48)	N/A	101

N/A –Exposures through identified route are not expected for the given population or subgroup.
[1] Aggregate MOE (food and residential) = 1/[(1/MOEwater) + (1/MOE oral) + (1/MOE dermal) + (1/MOE inhalation)]]

5. Occupational Exposure and Risk

For more detail on the occupational assessment, see the *Butoxypolypropylene Glycol: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision*, (Lloyd, August 2007).

Workers can be exposed to BPG through mixing, loading, applying a pesticide, or re-entering treated sites. Different from the residential risk assessment for handlers, the occupational risk assessment assumes a professional handles a much greater amount of pesticide than a residential user. Occupational handlers of BPG who are likely to be exposed include mixers, loaders, and applicators. Occupational risk for all of these potentially exposed populations is measured by the MOE. An MOE ≥ 100 has been determined to be adequately protective for both short-term (1 to 30 days) and intermediate-term (1 to 6 months) exposures for BPG handlers based on the standard uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variability. Long-term worker exposure to BPG is not expected.

BPG dermal and inhalation exposure was estimated using the Pesticide Handlers Exposure Database (PHED), Chemical Manufactures Association (CMA) data, and proprietary data. The quantitative exposure/risk assessment developed for occupational handlers is based on the following scenarios:

Mixer/Loader/Applicators:

1) Liquid: Low Pressure Handwand Sprayer;
2) Ready-To-Use Liquid: Pour On Applications;
3) Applying Wipe Applications;
4) Ready-To-Use: Trigger Pump Sprayer Applications;
5) Applying with Aerosol Cans.

All worker scenarios were assumed to be short- and intermediate-term in exposure durations (i.e., 1-30 days and 1-6 months). Since both toxicity endpoints selected for the short- and intermediate-term risk assessment are the same, the risk estimates are also the same.

Table 9 summarizes the combined short-/intermediate risks at different levels of personal protection. Baseline PPE includes long-sleeve shirt and long pants only, while single layer protection adds chemical resistant gloves. For most scenarios, risks are below the Agency's level of concern (i.e., the MOEs are greater than 100). Two occupational scenarios shown below have short- and intermediate-term dermal risks that exceed the Agency's level of concern (i.e., the MOEs are less than 100) for handlers at baseline PPE:

- Mixing/Loading/Applying Liquids with Low Pressure Handwand for Horses
- Applying Formulations via Wipe

However, with the addition of chemical-resistant gloves risks for both scenarios are below the Agency's level of concern.

Table 9: Short- and Intermediate-Term Combined MOEs for Handlers

Exposure Scenario	Animal or Site	Application Rate (lb ai/acre)	Use/ Day	MOE at Baseline PPE*	MOE at Baseline PPE + gloves
Mixer/Loader/Applicator (M/L/A)					
Mix/Load/Apply Emulsifiable Concentrates with Low Pressure Hand Wand	Livestock buildings/animal premises	0.04 lbs ai/gallon	40 gallons	440	NA**
	animal: dogs, cats	0.036 lbs ai/animal	16 animals	1,200	NA
	animal: horses, livestock	0.036 lbs ai/animal	400 animals	**Dermal:49** Inhalation: 29,000	Dermal: 11,000 Inhalation: 29,000
Applying Ready to Use Formulations via Pour-on (using PHED mix/load liquid)	animal: horses	0.036 lbs ai/animal	400 animals	1,700	NA

Table 9: Short- and Intermediate-Term Combined MOEs for Handlers					
Exposure Scenario	**Animal or Site**	**Application Rate (lb ai/acre)**	**Use/ Day**	**MOE at Baseline PPE***	**MOE at Baseline PPE + gloves**
Applying Formulations via Wipe (CMA data)	animal: horses	0.036 lbs ai/animal	8 animals	**Dermal: 85** Inhalation: 1,600	Dermal: 850 Inhalation: 1,600
Applying Ready to Use Formulations via Trigger-Pump Sprayer (using Propoxur Trigger Pump study)	indoor surfaces	0.036 lbs ai/gallon	2 gallons	68,000	NA
	animal: horses, foals	0.036 lbs ai/animal	400 animals	340	NA
Applying with Aerosol Cans	outdoor surfaces and/or space spray	0.33 lb ai/16 oz can	Four 16 oz bottles	260	NA

* MOEs less than 100 are identified in bold font.
** NA is "not assessed", since baseline risks do not exceed EPA's level of concern.

Post-Application Occupational Risk

The Agency does not believe there are any scenarios that are significant contributors to occupational post application exposure. Therefore, no post application scenarios have been assessed. Dermal and inhalation exposures for occupational handlers are not likely to occur from the registered uses of BPG. In addition, inhalation exposures for the post-application scenarios would account for a negligible percentage of the overall body burden if calculated. This is particularly true for BPG, which has a negligible vapor pressure at 25ºC**.**

B. Ecological Risk Assessment

The Agency has conducted an environmental fate and effects risk assessment for BPG for the purpose of making a reregistration decision. The Agency evaluated environmental fate and ecological studies submitted for BPG, and along with quantitative structure activity relationship modeling has determined that the data are adequate to support a reregistration decision.

A summary of the environmental risk assessment findings and conclusions is provided below. For more detail on the ecological exposure and risk assessment, see the *EFED RED Chapter for Butoxy Polypropyleneglycol*, (Odenkirchen, September 2007). For more information on the drinking water assessment see the *Drinking Water Assessment for the Reregistration Eligibility Document for butoxypolypropylene glycol*, (Khan, August 2007).

1. Environmental Fate and Transport

No guideline data have been submitted to the Agency that allow for an empirical assessment of the biotic and abiotic degradation processes for BPG. To address this lack

of data, the risk assessment used output from the EPISUITE v 3.20 model. The following predictions from the EPISUITE v 3.20 model output can be made for BPG:

- The compound will not volatilize (estimated vapor pressure 2.81 x 10^{-27} mm Hg at 25 ^{o}C).
- The compound will readily adsorb to organic carbon (estimated log K_{oc} 9.643).
- There is a low probability for biodegradation.
- There is limited potential for bioconcentration (estimated BCF 86).

2. Environmental Effects

a. Ecological Risk Estimation

To estimate potential ecological risk, EPA integrated the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to the Agency's levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

The majority of BPG use sites are considered to be indoors, and it is unlikely these use sites would significantly contribute to an outdoor exposure to the environment. However, there are animal applications for which application may occur outdoors and for which pathways to outdoor environments may exist. Animal applications are primarily on horses as insect repellent for biting insects that are a nuisance, such as horse flies, deer flies, horn fly, house fly, mosquitoes and gnats. Cats and dogs may also be treated directly.

For the purposes of the ecological risk assessment, treatment of horses is considered to be the most conservative application in terms of mass applied, opportunity for wildlife interaction, and opportunity for introduction of material to surface waters through wash-off. In the case of BPG, potential ecological organisms that could be affected would include freshwater and estuarine/marine vertebrates and invertebrates, aquatic plants, and birds gleaning parasites from treated livestock. Mammals, reptiles, terrestrial amphibians and terrestrial plants are not considered as it is assumed that no exposure pathways exist for these organisms from the registered uses of BPG.

3. Risk to Aquatic Organisms

There was little empirical information on the toxicity of BPG to aquatic organisms. Data are available to show low acute toxicity to freshwater fish and freshwater invertebrates. Gaps in the effects data were addressed through the application of quantitative structure activity relationships (QSAR) usingthe ECOSAR v0.99h model

to predict effects endpoints for chronic freshwater fish and invertebrates, as well as acute and chronic marine/estuarine fish, acute and chronic marine/estuarine invertebrates and aquatic plants.

The only aquatic RQ values exceeding Agency levels of concern levels are for estuarine/marine invertebrates, with an acute RQ of 0.15 (LOC for acute risks to listed aquatic species is 0.05) and a chronic RQ of 1.6 (LOC for chronic risks to listed aquatic species is 1.0). Although the LOCs are exceeded in the screening level risk assessment, these findings are considered to be extremely conservative. This is due to the very high application rate assumed (26 applications per year), the assumption that all material is washed from treated animals, that all material reaches a water body (despite the expected high affinity for soils), that all the material exists in water at a concentration orders of magnitude above estimated solubility limit, and that the concentration in water is unaffected by potential partitioning to sediment.

Given that the RQ values are just above screening levels of concern and the expectation that any departure from the conservative exposure assumptions would significantly lower estimated water concentrations, EPA believes there is sufficient information to conclude acute and chronic risks to estuarine/marine invertebrates do not exceed EPA's level of concern.

4. Risks to Birds

Three studies of acute effects on birds were available. Using TREX v 1.3.1 terrestrial risk assessment model, the available data were scaled to calculate LD50 values for different sizes of birds. The scaled LD50s for birds range from >1620 mg/kg for small 20 gram birds, to >2914 mg/kg for larger 1000 gram birds.

There are potential exceedances for listed small birds weighing 20 g (RQ is <9) and for birds of the 100 g weight class (RQ is <1.4). The LOC for listed terrestrial species is 0.1. It is important to note that there is considerable uncertainty in both the exposure and effects inputs to this RQ calculation. The exposure estimate represents a very conservative assumption that the entire mass of pesticide applied to a horse is bioavailable to birds consuming arthropod parasites on the livestock. Because of the large size of the BPG molecule and its low vapor pressure, gleaning birds would most likely be exposed through ingestion of the arthropod pests on which BPG is incidentally applied.

Comparing potential concentrations of BPG on insects, which range from 3800 mg/kg for small insects to 400 mg/kg for large insects, to the dietary acute toxicity endpoints, that are essentially levels demonstrated to have no effects in two tested species at the no observed adverse effects concentration (NOAEC) of 5620 mg/kg-diet, suggests that the dietary route is of minimal significance for birds. EPA therefore concludes that there is sufficient information to refute the hypothesis of adverse effects in birds periodically feeding on treated livestock.

5. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitats. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in the RED being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of BPG "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

IV. Risk Management and Reregistration Decision

The Agency has determined that butoxypolypropylene glycol is eligible for reregistration provided that the risk mitigation measures and label amendments specified in this RED are implemented. The following Table 10 provides a summary of the measures for managing risks associated with the use of butoxypolypropylene glycol.

Table 10: Summary of Risk Mitigation Measures

Risk of Concern	Mitigation Measure
Dermal risk to occupational handlers mixing, loading, and applying liquid concentrate products	Require chemical resistant gloves for mixers, loaders, and applicators using liquid concentrates.
Dermal risk to occupational handlers applying impregnated wipe products	Require chemical resistant gloves for applicators using impregnated wipes.

A. Human Health Risks

Residential

The Agency conducted human health risk assessments for dietary (drinking water) exposure, residential handlers and post-application residential exposure, and aggregated those activities that could lead to multiple exposures. All potential risks were below the

Agency's level of concern. Therefore, no risk mitigation is needed for residential uses of BPG.

Occupational

The Agency conducted a risk assessment on the occupational uses of BPG, including handlers that mix, load, and apply BPG in various ways. Two scenarios presented potential risk to handlers. The first scenario presented potential dermal risk concerns for mixers and loaders wearing baseline personal protection equipment (PPE) handling liquid soluble concentrations for application to horses and livestock. The addition of chemical resistant gloves will address this risk, and results in risk estimates below the Agency's level of concern. Therefore, to address potential dermal risk concerns for mixers, loaders, and applicators handling liquid soluble concentrate product, chemical resistant gloves are required.

The second scenario of potential concern is for handlers applying BPG using impregnated wipes. Applicators wearing baseline PPE would have potential dermal risk concerns. With the addition of chemical resistant gloves, the risk is below the Agency's level of concern. Therefore, to address potential dermal risk concerns for applicators handling impregnated wipe products, chemical resistant gloves are required.

B. Ecological Risks

Ecological Risks

From the screening level ecological risk assessment, the only RQ values above Agency concern levels are for birds and estuarine/marine invertebrates. Therefore, for all other evaluated taxa, risks do not exceed EPA's levels of concern and no mitigation is required.

For smaller birds in the 20 and 100 gram weight class, further evaluation of the most likely route of exposure (dietary) provides additional information that leads to a conclusion of no risks of concern. Similarly for estuarine/marine invertebrates, the conservative exposure assumptions and the slight exceedance of risk quotients above Agency concern levels suggests that risks to these species are overestimated in the screening-level assessment. There is sufficient information to conclude that the actual risks are not of concern. Therefore, no risk mitigation is necessary to address ecological risks.

V. What Registrants Need to Do

The Agency has determined that the products containing butoxypolypropylene glycol (PC 011901) are eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table 11. The Agency intends to issue Data Call-Ins (DCIs) requiring generic- and product-specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or

waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of BPG for currently registered uses has been reviewed and determined to be substantially complete. However, the guideline requirement listed below is necessary to confirm the reregistration eligibility decision documented in this RED.

Guideline Number: OPPTS 870.3050

The 28-day oral toxicity study is required for BPG because there are no repeat exposure oral toxicity studies on BPG, and incidental oral exposures are possible via exposure from its use on companion animals in residential settings. Since there are no repeated exposure (route-specific) studies, the Agency selected the endpoint and equivalent oral point of departure from the 90-day dermal toxicity study in rats.

The available data on BPG consists of acute oral, dermal, and inhalation data, a 90-day dermal toxicity study, and a dermal developmental toxicity study in rats. The Agency made a reasonable assumption that the oral route is not more toxic than the dermal route; that the dermal absorption rate is 12%, based on the material balance study in rats, and converted the dermal NOAEL to an oral NOAEL.

Submission of the 28-day oral toxicity study will allow the Agency to more accurately assess the potential risks resulting from repeated oral exposure. The oral toxicity data can help in refining incidental oral risk assessments, and assist in the effective management of health risks from drinking water and/or residential oral exposures. The registrant has agreed to conduct this 28-day oral toxicity study for BPG.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant 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 intends to issue a separate product-specific Data Call-In (PDCI), outlining specific data requirements including the ones listed below. For any questions regarding the PDCI, please contact Veronica Dutch at (703) 308-8585.

Guideline: 810 Product Performance Test Guidelines

Efficacy data are required for all products that are registered for use to repel public health pests. BPG is registered to repel a number of pests that require this type of data, including: Deer flies, gnats, horse flies, house flies, bot flies, horn flies, mosquitoes, stable flies, chiggers, lice, ticks, wasps, fleas, biting flies, chiggers, bed bugs, ants (only for claims for fire ants, harvester ants, pharoah ants), and roaches.

Additional information on the efficacy data can be found in the Series 810 Product Performance Test Guidelines on the Agency's website. (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/810_Product_Performance_Test_Guidelines/index.html)

Guideline: OPPTS 870.7200

Because BPG is registered for use on animals, the companion animal study (OPPTS 870.7200) is required in both cats and dogs. The companion animal study is required to see if there is an adequate margin of safety for use on both dogs and cats.

The most likely exposure scenario for dogs and cats is dermal exposure. In the absence of the companion animal safety data, the Agency makes an assumption that BPG is not toxic to pets based on the results from laboratory dermal studies in the rat, where no systemic toxicity was observed at the limit dose (1000 mg/kg/day) and no developmental toxicity was observed at 4000 mg/kg/day.

A companion animal study in cats and dogs will provide information on the possible health hazards to companion animals. If the companion animal safety study shows toxicity to pets, changes to the product labeling may be needed.

The submission of companion animal safety study would provide necessary data to determine if an adequate margin of safety exists for the companion animal when the products are used according to the product labeling. The general public will benefit if the Agency can more accurately assess the potential risks to companion animals.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language required to incorporate these changes is provided in Table 11.

Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 11: Summary of Labeling Changes for Butoxypolypropylene Glycol (PC 011901)

Description	Amended Labeling Language for Manufacturing Use Products	Placement on Label
For all Manufacturing Use Products	"Only for formulation into a repellent for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] For Liquid Concentrate Formulations (including emulsifiable or soluble concentrates)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (registrant inserts correct chemical-resistant material). "If you want more options, follow the instructions for category" [registrant inserts A,B,C,D,E,F,G,or H] "on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: > Long-sleeved shirt and long pants, > Shoes plus socks, and > Chemical-resistant gloves."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] For All Ready-To-Use Formulations (including pour-ons, repellent sticks, roll-ons, trigger sprayers, aerosol sprayers) **except** impregnated wipes	"Personal Protective Equipment (PPE)" "Applicators, and other handlers must wear: > Long-sleeved shirt and long pants, and > Shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] For Impregnated Wipe Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (registrant inserts correct chemical-resistant material). "If you want more options, follow the instructions for category" [registrant inserts A,B,C,D,E,F,G,or H] "on an EPA chemical-resistance category selection chart."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	"Applicators, and other handlers must wear: > Long-sleeved shirt and long pants, > Shoes plus socks, and > Chemical-resistant gloves."	
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards Statement	"ENVIRONMENTAL HAZARDS" "Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements." For indoor products packaged in containers equal to or greater than 5 gallons or 50 lbs add the following statement: "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of	Precautionary Statements immediately following the User Safety Recommendations

	a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	
Entry Restrictions for liquid concentration or liquid ready-to-use products labeled for premises or bedding use	"When used on animal premises or bedding, do not enter or allow others to enter until sprays have dried."	Directions for Use Under General Precautions and Restrictions
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Direction for Use
Other Application Restrictions	*All products:* "Not for use on meat or dairy animals, poultry, horses or foals intended for slaughter." "Not for use in farm structures or buildings housing food producing animals or poultry, or in milk rooms." *All products applied as a spray:* "Only spray in a well ventilated area." "Do not spray product when food is present." *For products applied to pets or animals:* "Do not allow product to contact animal's eyes, nose, mouth, or sores during application." "Do not use on foals, puppies or kittens under 12 weeks old." *For products applied to pet or other animal premises:* "Remove pets or animals when spraying animal premises."	Directions for Use

Other Application Restrictions	All application rates must be stated on product labels that are consistent with the rates supported in Appendix A. All rates must be expressed in terms the applicator can use in order to arrive at the maximum application rate. For example, for sprays to animals the duration of the spray must be included (e.g., 3 seconds per side; 6 sides).	Directions for Use
End Use Products Intended for Residential Use		
Application Restrictions	"Do not apply this product in a way that will contact any person, pet*, either directly or through drift. Keep people and pets* out of the area during application." * ***Note:*** For products with direct pet uses, delete the reference to pets on these statements.	Directions for Use under General Precautions and Restrictions
Entry Restrictions for end-use products with directions for use on animal premises	"When used on animal premises or bedding, do not allow people or pets* to enter the treated area until sprays have dried." * ***Note:*** For products with direct pet uses, delete the reference to pets on these statements.	Directions for use under General Precautions and Restrictions
Other Application Restrictions	The application restrictions listed above for occupational use products also apply to residential use products.	Directions for Use

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Appendices

Appendix A. Non-Food/Non-Feed Uses Eligible for Reregistration
Butoxypolypropylene glycol (011901)
Case No. 3123

Use Site	Form Code	Max.App Rate/App	Unit	Minimum Re-treatment Interval (days)	Limitations
AGRICULTURAL/ FARM PREMISES	EC	0.04	lb ai/gal	NS	Do not apply to plant foliage. Not for use in farm structures or buildings housing food producing animals or poultry, or in milk rooms.
	RTU	0.33	lb ai/ 16 oz. can		
ANIMAL KENNELS/SLEEPIN G QUARTERS (COMMERCIAL)	EC, PRL	0.04	lb ai/gal	NS	Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not apply to plant foliage. Not for use in farm structures or buildings housing food producing animals or poultry, or in milk rooms.
	RTU	0.036	lb ai/gal		
DOGS/CANINES (ADULTS/PUPPIES)	PRL, RTU, Wipes	0.036	lb ai/animal	3	Do not treat animals under 12 weeks of age. Do not apply to humans. Do not allow product to contact animal's eyes, nose, mouth, or sores during application.
CATS (ADULTS/KITTENS)	PRL, RTU	0.036	lb ai/animal	3	Do not treat animals under 12 weeks of age. Do not apply to humans. Do not allow product to contact animal's eyes, nose, mouth, or sores during application.
HORSES (SHOW/RACE/SPECI AL/PONIES)	EC, PRL, RTU, Wipes	0.036	lb ai/animal	1	Remove animals prior to treatment. Do not apply to plant foliage. Do not treat animals under 6 weeks of age. Remove feed and water prior to treatment. Not for use on meat or dairy animals, poultry, horses or foals intended for slaughter. Do not allow product to contact animal's eyes, nose, mouth, or sores during application.
PET LIVING/SLEEPING QUARTERS	PRL, RTU	0.036	lb ai/gallon	NS	Remove food and animals from premises prior to treatment. Not for use in farm structures or buildings housing food producing animals or poultry, or in milk rooms.

NS: Not Specified
EC: Emulsifiable Concentrate
PRL: Pressurized Liquid
RTU: Ready to Use

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

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the dodine case covered by this RED. It contains generic data requirements that apply dodine in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Data Requirement			Use Pattern	Citations
New Guideline Number	Old Guideline Number	Description		
PRODUCT CHEMISTRY				
830.7200	63-5	Melting Point	All	42541403
830.7220	63-6	Boiling Point/boiling range	All	42541403
830.7300	63-7	Density	All	42541403
830.7370	63-10	Dissociation Constants in Water	All	42541403
830.7550	63-11	Partition coefficient, shake flask method	All	42541403
830.7840	63-8	Solubility	All	42541403
ECOLOGICAL EFFECTS				
850.2200	71-2	Avian Dietary Toxicity	C, K	43117501, 43117502
850.1075	72-1	Acute Toxicity to Freshwater Fish	C, K	42753302
850.1010	72-2	Acute Toxicity to Freshwater Invertebrates	C, K	42753301
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat	All	41884504
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	All	41884503
870.1300	81-3	Acute Inhalation Toxicity – Rat	All	00071332
870.2400	81-4	Primary Eye Irritation - Rabbit	All	41884501
870.2500	81-5	Primary Skin Irritation	All	41884502
870.3050	None	Repeated Dose 28-day Oral Toxicity Study in Rodents	K	DATA GAP
870.3250	82-3	90-Day Dermal Toxicity – Rat	All	42269901
870.3700A	83-3A	Developmental Toxicity – Rat	All	42815501
870.4100B	83-1B	Chronic Feeding Toxicity Study - Non-rodent	All	00081467
870.5265	None	Microbial Gene Mutation (Ames assay)	All	41886202
870.5395	84-2	In Vitro Mammalian Cytogenetics Tests	All	41886201
870.5900	84-2	Sister Chromatid Exchange (SCE)	All	41886203
Special Study	None	Material Balance Study in Rats	All	43349901
OTHER				
Special Study	None	Trigger Spray Study - Inhalation and Dermal Exposure	All	41054701 (Propoxur)
Special Study	None	Wipe and Sponge Application Data – Inhalation and Dermal Exposure	All	Chemical Manufacturers Association (CMA) Data
Special Study	None	Handler Application Data – Inhalation and Dermal Exposure	All	ORETF Chemical Handlers Exposure Studies

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, EPA-HQ-OPP-2007-1090.

It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 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:www.epa.gov/pesticides/reregistration

These documents include:

HED Document:

Butoxypolypropylene Glycol: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). Lloyd, M., et al. D338969, September 2007.

Butoxypolypropylene Glycol: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision. Lloyd, M. D338970, August 27, 2007.

EFED Document:

EFED RED Chapter for Butoxy Polypropyleneglycol. Odenkirchen, E. D338964, September 2007.

Drinking Water Assessment for the Reregistration Eligibility Document for butoxypolypropylene glycol. Khan, F. D338965. August 21, 2007.

Appendix D. Bibliography

MRID	Citation Reference
71332	Freeman, J.J.; Robbins, G.R. (1980) Acute Inhalation Toxicity Study in Rats: C.S.E. Study #0454C. (Unpublished study received Jan 9, 1981 under 4816-538; prepared by Cosmopolitan Safety Evalua- tion, Inc., submitted by Fairfield American Corp., Medina, N.Y.; CDL:244170-A)
81467	Weil, C.S.; Palm, P.E. (1958) Special Report on One Year of Oral Doses of Crag Fly Repellent to Dogs: Report 21-24. (Unpublished study received Jan 6, 1968 under 8F0694; prepared by Univ. of Pittsburgh, Mellon Institute of Industrial Research, Industrial Fellowship, submitted by Union Carbide Corp., New York, N.Y.; CDL:091203-D)
41054701	Knarr, R. (1988) Exposure of Applicators to Propoxur During Trigger Pum Spray Application of a Liquid Product: 99100. Unpublished study prepared by Mobay Corp. 195 p.
41884501	Myers, R.; Christopher, S. (1991) Stabilene Fly Repellent: Primary Eye Irritancy Study in the Rabbit: Lab Project Number: 53-160. Unpublished study prepared by Bushy Run Research Center. 22 p.
41884502	Myers, R.; Christopher, S. (1991) Stabilene Fly Repellent: Primary Skin Irritancy Study in the Rabbit: Lab Project Number: 53-159. Unpublished study prepared by Bushy Run Research Center. 21 p.
41884503	Myers, R.; Christopher, S. (1991) Stabilene Fly Repellent: Acute Percutaneous Toxicity Study in the Rabbit: Lab Project Number: 53-158. Unpublished study prepared by Bushy Run Research Center . 21 p.
41884504	Myers, R.; Christopher, S. (1991) Stabilene Fly Repellent: Acute Peroral Toxicity Study in the Rat: Lab Project Number: 53-157. Unpublished study prepared by Bushy Run Research Center. 21 p.
41886201	Vergnes, J.; Morabit, E. (1991) Stabilene Fly Repellent: Determination of in vivo Clastogenic Potential Using the Micronucleus Test wth Swiss-Webster Mice: Lab Project Number: 54-4. Unpublished study prepared by Bushy Run Research Center (Union Carbide). 45 p.
41886202	Vergens, J.; Morabit, E. (1991) Stabilene Fly Repellent: Determina- tion of Mutagenic Potential in the Salmonella/Microsome (Ames) Assay: Lab Project Number: 53-153. Unpublished study prepared by Bushy Run Research Center (Union Carbide). 42 p.
41886203	Vergnes, J.; Morabit, E. (1991) Stabilene Fly Repellent: Determina- tion of Chemical Effects Upon Sister Chromatid Exchanges in Cultured Chinese Hamster Ovary Cells: Lab Project No: 53-163. Unpublished study prepared by Bushy Run Research Center (Union Carbide). 41 p.
42269901	Wagner, C.; Loughran, K.; Gill, M. (1992) Stabilene Fly Repellent: Ninety-Day Repeated Cutaneous Dose Toxicity Study in Fischer 344 Rats: Lab Project Number: 54-96. Unpublished study prepared by Bushy Run research Center. 468 p.
42541403	Matlock, P. (1989) Stabilene Fly Repellant: Product Chemistry Data (1987): ?Series 63|. Unpublished study prepared by Union Carbide Corp. 5 p.
42753301	Waggy, G. (1993) Acute Toxicity of Stabilene Fly Repellent to Daphnia magna: Lab Project Number: 93010802: 302. Unpublished study prepared by Union Carbide Technical Center. 25 p.
42753302	Waggy, G. (1993) Acute Toxicity of Stabilene Fly Repellent to Pimephales promelas (fathead minnows): Lab Project Number: 93010801: 301. Unpublished study prepared by Union Carbide Technical Center. 26 p.
42815501	Neeper-Bradley, T.; Kubena, M. (1993) STABILENE Fly Repellent: Developmental Toxicity Study of Cutaneous Administration in CD (Sprague-Dawley) Rats: Lab Project Number: 91U0029. Unpublished study prepared by Bushy Run Research Center, Union Carbide Chemicals and Plastics Co. Inc. 446 p.

43117501 Campbell, S.; Beavers, J. (1994) Stabilene: A Dietary LC50 Study with the Mallard: Lab Project Number: 142-145. Unpublished study prepared by Wildlife International Ltd. 17 p.
43117502 Campbell, S.; Beavers, J. (1994) Stabilene: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 142-144. Unpublished study prepared by Wildlife International Ltd. 18 p.
43349901 Morris, E.; Beskitt, J. (1994) STABILENE Fly Repellent: Material Balance Study Following Oral and Cutaneous Administration to Female Sprague Dawley Rats: Revised Report: Lab Project Number: 92U1076 REVISED. Unpublished study prepared by Bushy Run Research Center. 105 p.

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Hazard Characterization Section for the Reregistration Eligibility Decision. Byong-Han Chin, Ph.D. D338972. August 27, 2007.

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Appendix E. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available via the Agency's website at *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 hard copy 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 *http://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 §156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR §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 22161-0002

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 at *http://www.ncis.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:

- Date of receipt;
- EPA identifying number; and
- 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.