DATE: January 25, 2006

MEMORANDUM

SUBJECT: ***TRIETHYLENE GLYCOL:*** Revised Antimicrobials Division's Review of the Disciplinary Sciences for Issuance of the Reregistration Eligibility Decision (RED) Document. Reregistration Case No.: 3146. PC Code: 083501. CAS Registry No.: 112-27-6. DP#: 305169.

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Attached is the Antimicrobials Division's (AD) risk assessment supporting issuance of a Reregistration Eligibility Decision (RED) for the active ingredient, Triethylene Glycol, as well as a

reassessment of the tolerances for the inert agricultural uses of this chemical. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate and ecotoxicity of triethylene glycol.

Based on its review and evaluation of all available information, AD concludes that there is a reasonable certainty of no harm to the general population nor to infants and children in particular, resulting from triethylene glycol exposure as an active ingredient in air sanitizers and surface disinfectants, and as an inert ingredient in agricultural pesticide formulations. As a result, AD has determined that a qualitative approach to assessing human health risks from exposure to this compound is appropriate.

The supporting documentation used to generate the triethylene glycol risk assessment is listed below:

1. Background Document on Triethylene Glycol Product Chemistry and Environmental Fate Data Requirements. (Case#: 3146) (Memorandum: N. Shamim, 8/13/03).

2. ***TRIETHYLENE GLYCOL*:** Revised Toxicology Chapter in Support of Issuance of the Registration Eligibility Decision (RED) Document. PC Code: 083501. Reregistration Case Number: 3146. CAS Registry Number: 112-27-6. DP#: 325786 (Memorandum: M. Centra, 10/11/05).

3. ***TRIETHYLENE GLYCOL:*** Revised Report of the Antimicrobials Division Toxicology Endpoint Selection Committee (Memorandum: T. McMahon, 11/21/05).

4. EPA ID # 083501: Triethylene glycol. Review of Phase IV response submissions in support of FIFRA 88. EPA Record No. S444604, S444216. Caswell No. 888. PC Code: 083501. HED Project No(s). D193163, D192934. (Memorandum: G. Reddy, 12/22/93, TXR #: 010715).

5. AD's Occupational and Residential Exposure Chapter for the Triethylene Glycol Reregistration Eligibility Decision (RED) Document (Case No. 3146). PC Code 083501 (Memorandum: T. Leighton, 9/26/03).

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

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

8. Ecological Hazard and Environmental Risk Science Chapters for the Triethylene Glycol RED (Memorandum: K. Montague, 8/28/03).

9. Science Chapter on: Environmental Fate Studies and Environmental Fate Assessment of Triethylene Glycol (Memorandum: N. Shamim, 8/13/03).

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1.0 EXECUTIVE SUMMARY

This document addresses the exposures and risks from use of triethylene glycol as an active ingredient in air sanitizers/hospital disinfectants, and as an inert ingredient in agricultural pesticide formulations. Potential residential exposures and risks are also addressed pursuant to the language and intent of the Food Quality Protection Act (FQPA).

1.1 Regulatory History

Active ingredient Status

The active ingredient, triethylene glycol, was first registered in 1947 by the FDA for use in hospitals as an air disinfectant. As an active ingredient, triethylene glycol is formulated primarily as a pressurized liquid and is used in two types of applications: air sanitizers/hospital disinfectants, and pest (mites and red lice) control on caged birds.

Inert Ingredient Status

As an inert ingredient, triethylene glycol facilitates delivery of formulated pesticide chemical products that are used as herbicides, fungicides, insecticides, growth regulators and attractants on a wide variety of agricultural commodities.

Tolerance Exemptions

The following tolerance exemption for triethylene glycol is listed in 40 CFR 180.920:

1. Triethylene glycol is exempted from the requirement of a tolerance when used as a deactivator in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only

2. In addition to the above, triethylene glycol is approved by the Food and Drug Administration (FDA) as a preservative for food packaging adhesives as listed in 21 CFR 175.105. Currently, however, there are no EPA registered products for this use.

3. Triethylene glycol also has an indirect food additive regulation (21 CFR 177.1200) for its use as a plasticizer in cellophane. This use is regulated by the FDA.

1.2 Hazard Profile

Published literature studies submitted by the CSPA Glycols Joint Venture consortium show low toxicity (Toxicity Categories III and IV) following acute exposures by the oral, dermal, and inhalation routes. Triethylene glycol produces mild and slight irritation to the eyes and skin, respectively. In addition, triethylene glycol is not a dermal sensitizer. Repeat dose toxicity studies by the oral, dermal, and inhalation routes at doses near or above the limit doses for such studies (1000 mg/kg/day for oral and dermal studies, 1000 mg/m^3 for inhalation studies) have also

shown a lack of systemic toxicity or toxicity only at doses in excess of the limit dose. Triethylene glycol administered orally to experimental animals in studies designed to measure developmental and reproductive toxicity was without any significant effect at doses up to and including a limit dose. Chronic exposure of experimental animals to triethylene glycol at doses equivalent to or in excess of the limit dose for such studies has shown the chemical to be without adverse toxic effects. Triethylene glycol has been shown to be negative for mutagenicity in a variety of assays and has also been shown to be negative for carcinogenicity in experimental animals.

Based on a review of the available toxicology data, the Antimicrobials Division concluded that triethylene glycol is of very low toxicity by the oral, dermal, and inhalation routes of exposure. The toxicology database is adequate to characterize the hazard of triethylene glycol, and no data gaps have been identified. There are no indications of special sensitivity of infants or children resulting from exposure to triethylene glycol. Therefore, the special 10x hazard-based safety factor under FQPA is not required.

1.3 Dietary Exposure and Risk

Dietary exposure could potentially occur from the use of triethylene glycol as a preservative in food packaging adhesives, and from its use as an inert ingredient in agricultural pesticide formulations. For such inert uses, the Agency has developed a screening-level assessment tool with highly conservative assumptions regarding exposure to a generic inert used in such a manner. In this model, the following assumptions are made: (1) actual crop-specific residue data for active ingredients can be used as surrogate data for inert ingredient residue level; (2) the inert ingredient is assumed to be used on all crops; (3) 100% of all crops are "treated" with the inert ingredient; and (4) no adjustment is made for the percentage of the inert in the formulation, application rate, or multiple applications of different active ingredient formulations. The results of this modeling represent an upper-bound estimate of likely dietary exposure to an inert resulting from preharvest use. An estimated acute and chronic dietary exposure of less than 1 mg/kg/day is made from this model. This value is orders of magnitude below the levels at which effects are observed from exposure to triethylene glycol as noted in the hazard profile, and thus dietary exposure does not present any risk of concern.

1.4 Occupational/Residential Exposures and Risks

Although there is potential inhalation and dermal handler exposure to triethylene glycol from use as an air sanitizer, surface disinfectant, and insecticide for control of mites and red lice in bird cages, no toxicological endpoints of concern have been identified for this chemical, based on its low order of toxicity. In addition to potential dermal and inhalation handler exposure, there is the potential for postapplication exposure to individuals reentering treated rooms and/or contacting sprayed surfaces. The Office of Prevention, Pesticides and Toxics (OPPT) has developed a model, EFAST (Exposure and Fate Assessment Screening Tool), to estimate air concentrations. EFAST bases its estimates on physical/chemical properties. Modeled results indicate a screening-level, high end, peak concentration of 8.54 mg/m^3. This exposure estimate, while highly

conservative, is orders of magnitude below concentrations at which effects were observed in inhalation studies with experimental animals (levels in excess of the limit concentration of 1000 mg/m^3) and thus postapplication exposure does not present a risk of concern.

1.5 Ecological Toxicity

As a result of the Phase IV review of triethylene glycol for reregistration under FIFRA, ecological effects data requirements were waived due to the intended use of triethylene glycol as an indoor microbiocide, its high volatility, and known low toxicity (it is a preferred solvent for aquatic organism toxicity tests). Data obtained from published studies provide additional confirmation of the low toxicity of the compound to fish and aquatic invertebrates and show LC_{50} values ranging from 10,000 to 77,400 ppm.

1.6 Environmental Risk

For the RED, the Agency has relied on readily available open literature data that characterizes the fate properties of triethylene glycol. The results of these studies indicate that triethylene glycol is miscible in water, mobile in soils and stable to abiotic degradation hydrolysis and soil and aquatic photolysis. Biodegradation is expected to proceed rapidly in surface waters based on a number of River Dye-away tests (complete mineralization between 7 and 11 days) and will degrade in soils in days (primary degradation) to weeks (complete mineralization) based on sludge innoculum studies and predictions of ready biodegradability.

The estimated environmental concentrations of triethylene glycol from use as an active ingredient (indoor use) and from agricultural and non-agricultural (outdoor) inert uses in surface water would not likely exceed a peak (24-hour time averaged) concentration of 885 ppb or an annual average (single year) concentration of 29 ppb. Estimated concentrations in ground water would not likely exceed 106 ppb. Estimated exposures from indoor use of triethylene glycol as the active ingredient and/or as an inert ingredient are unlikely to result in surface water concentrations greater than those from outdoor uses. The estimated dose from the highest estimated environmental concentration of 885 ppb would be approximately 0.025 mg/kg/day, an intake that is orders of magnitude below the level at which effects are observed from exposure to triethylene glycol. Thus, estimated concentrations in drinking water do not present any risks of concern.

1.7 Conclusions

From the available animal studies and other data, EPA concludes that triethylene glycol exhibits low toxicity and that there is a reasonable certainty of no harm to the general population as well as infants and children from aggregate exposures to triethylene glycol as both an active or inert ingredient, including all anticipated dietary (food and water) exposures and all other types of exposures for which there is reliable information.

2.0 USE PROFILE

Triethylene glycol is an aliphatic alcohol prepared from ethylene oxide and ethylene. It is produced commercially as a by-product of ethylene glycol production; formation of an ether-ester of $HCOCH_2COOH$ with glycol followed by hydrogenation.[1]

The major applications for triethylene glycol are as (1) a dehydration agent for natural gas, (2) a humectant in printing inks, gums, resins and tobacco, (3) a non-volatile industrial solvent, emulsifier and extractant, (5) a lubricant in printing inks, textile dyeing, pharmaceuticals and cosmetics, (6) a plasticizer in the manufacture of vinyl, polyester, polyurethane resins, cellophane, glue, cork, powdered ceramics and some plastics and (7) a heat transfer medium. It is also used in the synthesis of some organic derivatives.

As an air sanitizer, this active ingredient has numerous listed active use sites including household or domestic dwellings, automobiles, taxis, limousines, hospitals, commercial and industrial equipment, laundry equipment, bathroom premises, refuse and solid waste containers, and hard non-porous surface treatments.

As an inert ingredient, triethylene glycol facilitates delivery of formulated pesticide chemical products that are used as herbicides, fungicides, insecticides, growth regulators and attractants on the following commodities: alfalfa, alfalfa (forage), almonds, apples, apricots, artichokes, arugula (foliar treatment), asparagus, atenoya, avocados, bananas, barley, barley (grain crop), beans, crensahw melons, beans (all or unspecified), beech nuts, beets (all or unspecified), black sapote, black walnuts, blackberries, blueberries, boisenberries, brazil nuts, broccoli, broccoli raab, brusselsprouts, butternuts, cabbage, canistel, cantaloupes, carambolas, carrots, cashews, cauliflower, celeriac, celery (all or unspecified), cherries, chestnuts, chinese mustard (foliar treatment), chinese cabbage, chinquapin (forest), fallow or idle agricultural land chive, christmas tree plantations, citrus fruits (all or unspecified), citrus hybrids, clover, cocoa, coffee, collards, conifers, corn (all or unspecified), corn (sweet), corn (field and/or foliage), corn (pop), cotton (all or unspecified), crabapples, cranberries, cucumbers, cucurbits, currants, dandelion, deciduous fruit, dill, eggplant, endive, field corn, grapefruit, filberts, flax (all or unspecified), flue-cured tobacco, forage and fodder grasses, garlic, gooseberries, gourds, grapes, guava, hickory nuts, honey ball melons, honeydew melons, hops, kale, kiwi, kohlrabi, kumquats, leafy vegetables, lemons, lettuce (all or unspecified), limes, litchi nuts, loganberries, loquats, macadamia nuts, mamey sapote, mangos, melons, mint (all or unspecified), muskmelons, mustard (all or unspecified), nectarines, nonbearing deciduous fruits, nuts, oats, oats (grain crop), olives (all or unspecified), onions (dry), oranges (all or unspecified), papayas, parsley, parsnips, passion fruit, pastures (all or unspecified), peaches, peanuts (all or unspecified), pears, peas, pecans, peppermint, peppers (non-bell type), peppers sweet (bell type), peppers, pineapple, pistachio nuts, plums, potatoes, proso millet, prunes, pumpkin, quinces, radishes, rangeland (all or unspecified), rape (all or unspecified), raspberries, rice (grain), rutabagas, rye (grain crop), safflowers,

sapodillaseed, silage, sorghum (all or unspecified), sorghum, sorghum (forage or fodder), soybeans (all or unspecified), spinach, squash, star apple, stone fruits (unspecified) strawberries, succulent lima beans, sudangrass (forage or fodder), sugar apple, sugar beets (all or unspecified), sugarcane (sugar crop), summer squash, sweet potatoes, swiss chard, tangelos, tangerines, tobacco, tomatoes, triticale (grain crop), turnips, walnuts, wastelands, watercress, watermelons, wheat (grain crop).

The active ingredient, triethylene glycol, was first registered by the EPA as an air sanitizer on August 3, 1948 (James Varley & Sons' Glyco Mist, EPA Reg. No. 421-21). The majority of the triethylene glycol formulated pesticide product producers are 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., Medo Industries, Inc., S.C. Johnson & Son, Waterbury Companies, Inc. and Chase Products Co.

Triethylene glycol is formulated primarily as a pressurized liquid and is used in two types of applications: air sanitizers/hospital disinfectants and pest (mites and red lice) control on caged birds. For each use category, Table 1 lists the registrants and their respective EPA registration numbers for products containing triethylene glycol (0.1 to 9.15% active ingredient).

Table 1. EPA Registration Numbers for Triethylene Glycol Products

Use Category	Formulation	Companies	EPA Registration Numbers
Air Sanitizer/ Disinfectant	Pressurized Liquid	S. C. Johnson & Son, Inc.	4822-293, -531
Air Sanitizer/ Disinfectant	Pressurized Liquid	Waterbury Companies, Inc.	9444-19, -136
Air Sanitizer/ Disinfectant	Pressurized Liquid	Amrep, Inc.	10807-7, -24, -26, -37, -38, -39, -43, -72
Air Sanitizer/ Disinfectant	Pressurized Liquid	Quest Chemical Corporation	44446-20
Air Sanitizer/ Disinfectant	Pressurized Liquid	Medo Industries, Inc.	51838-1, -2
Mite and Lice Control	Pressurized Liquid	Speer Products, Inc.	11715-20

In 1997, the Office of Pesticide Programs, Health Effects Division conducted an evaluation of the toxicity of the active ingredient, triethylene glycol as required by law under FIFRA for the reregistration of pesticidal chemicals.

The triethylene glycol mammalian toxicity database consisted of published literature studies and monographs submitted by the Glycols Joint Venture as a result of the Phase IV review of

triethylene glycol for reregistration under FIFRA. These submitted data were reviewed by the Agency and classified as acceptable or waived as indicated below in Table 2. At that time, these data were determined to satisfy the Subdivision F test guideline requirements and no additional data requirements were identified for the non-food use of triethylene glycol.[1]

Table 2. Data Requirements for Non-Food Use of Triethylene Glycol (1997)			
Guideline Number	**Study Type**	**Required**	**Satisfied**
§ 81-1	Acute Oral - Rat	Yes	Yes
§ 81-2	Acute Dermal - Rabbit	Yes	Waived
§ 81-3	Acute Inhalation - Rat	Yes	Yes
§ 81-4	Primary Eye Irritation	Yes	Yes
§ 81-5	Primary Dermal Irritation	Yes	Yes
§ 81-6	Skin Sensitization	Yes	Yes
§ 82-1a	Subchronic Oral - Rodent	No	No
§ 82-1b	Subchronic Oral - Non Rodent	Yes	Yes
§ 82-2	21-Day Dermal	Yes	Yes
§ 82-4	90-Day Inhalation	Yes	Yes
§ 83-3a	Developmental Toxicity - Rodent	Yes	Yes
§ 83-3b	Developmental Toxicity - Non Rodent	Yes	Yes
§ 83-4	Reproductive Toxicity - Rodent	Yes	Yes
§ 83-1b	Chronic Toxicity - Non Rodent	Yes	Yes
§ 83-1a	Carcinogenicity - Rodent	Yes	Yes
§ 84-2	Gene Mutation - Ames	Yes	Waived[a]
§ 84-2	Cytogenetics - Structural Chromosomal Aberration	Yes	Waived[a]
§ 85-1	General Metabolism	Yes	Yes

[a]The data waivers granted by the Agency in 1997 for the triethylene glycol mutagenicity assays are no longer applicable to this chemical. Several mutagenicity assays submitted to the Agency's Office of Prevention, Pesticides and Toxics were reviewed by OPP's Antimicrobials Division and determined to be acceptable/non-guideline studies. These four mutagenicity studies have been incorporated into the toxicity data base for triethylene glycol.

Tolerance Exemptions

The following tolerance exemption for triethylene glycol is listed in 40 CFR 180.920:

1. Triethylene glycol is exempted from the requirement of a tolerance when used as a deactivator in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only

2. In addition to the above, triethylene glycol is approved by the Food and Drug Administration (FDA) as a preservative for food packaging adhesives as listed in 21 CFR 175.105. Currently, however, there are no EPA registered products for this use.

3. Triethylene glycol also has an indirect food additive regulation (21 CFR 177.1200) for its use as a plasticizer in cellophane. This use is regulated by the FDA.

3.0 PHYSICAL AND CHEMICAL PROPERTIES

Triethylene glycol (CAS Registry Number: 112-27-6) is a colorless to pale straw-colored, essentially odorless, viscous, hygroscopic liquid with the following chemical properties: molecular weight of 150.20 amu, boiling point of 285 ^{o} C at 760 mm Hg and 165 ^{o} C at 14 mm Hg, melting point of - 5 ^{o}C (- 7 ^{o} C), specific gravity of 1.1274, vapor pressure of 0.01 mm Hg at 20 ^{o} C (0.00132 mm Hg at 25 ^{o} C), Log K_{OW} (octanol/water partition coefficient) of -1.75, Henry's Law Constant (air/water partition coefficient) of 3.1 x 10^{-11} atm m^3/mole and K_{OC} (organic carbon ratio in soil) of 10. Triethylene glycol does not absorb UV light at wavelengths above 290 nm. It is highly miscible in water and is soluble in alcohol, benzene and toluene. Triethylene glycol is practically insoluble in aliphatic hydrocarbons and fats is insoluble in petroleum ether and many common solvents. [2 - 8]

Common Name:	Triethylene Glycol
Chemical Name:	1,2-Bis(hydroxyethoxy)ethane, 2,2'-[1,2-Ethanediylbis(Oxy)], Bisethanol Ethanol, 2,2'-[1,2-Ethanediylbis(Oxy)]Bis
Molecular Formula:	$C_6H_{14}O_4$
Structure:	$OH\text{-}CH_2\text{-}CH_2\text{-}O\text{-}CH_2\text{-}CH_2\text{-}O\text{-}CH_2\text{-}CH_2\text{-}OH$

4.0 HAZARD PROFILE

Acute Toxicity

Published literature studies submitted by the Glycols Joint Venture consortium show low toxicity (Toxicity Categories III and IV) following acute exposures (Table 3). The acute oral and dermal toxicity of the chemical appears to be low, with reported oral LD_{50} values ranging from 15-22 g/kg compiled from monographs and review articles. The data available on acute dermal toxicity were insufficient to establish a dermal LD_{50}, but the data requirement was waived based on the low order of toxicity observed in other studies with triethylene glycol. Data on inhalation toxicity showed a maximum tolerated level of 800 mg/m^3 in rats, but intratracheal instillation of 0.25 cc undiluted chemical caused marked pulmonary irritation, edema, and later, fibrosis and abcess formation in these animals (intratracheal instillation is not an accepted route of administration for the Agency's toxicity testing guidelines). Published literature data on the skin and eye irritation as well as skin sensitization showed triethylene glycol to be non-irritating to the skin and eye (when tested at the limit doses established by the Agency for acute toxicity testing) and not a dermal sensitizer. [1, 8, 9, 10]

Triethylene glycol was evaluated for acute inhalation toxicity in male and female Sprague-Dawley albino rats in a study submitted to the Agency's Office of Toxic Substances. A review of this study by the Antimicrobials Division established a four hour LC_{50} greater than 5.2 mg/L, and places acute inhalation in Toxicity Category IV. Based on these results, this study was determined to be adequate for regulatory purposes and it now replaces the earlier submitted acute inhalation information. [11] (=5200mg/M^3)

Table 3. Acute Toxicity Profile of Triethylene Glycol

Guideline	Study Type	MRID No.	Results	Toxicity Category
870.1100	Acute Oral Toxicity	42814404	LD_{50} = 15-22 g/kg	IV
870.1200	Acute Dermal Toxicity	42814404	LD_{50} not determined	Study requirement waived
870.1300	Acute Inhalation Toxicity	OTS0527779-2	LC_{50} > 5.2 mg/L	IV
870.2400	Acute Eye Irritation Toxicity	42814404	mild irritant	III
870.2500	Acute Skin Irritation Toxicity	42814404	slight irritant	IV
870.2600	Skin Sensitization	42814404	non- sensitizer	N/A

N/A = Not applicable

Subchronic Toxicity

Repeat oral dosing studies conducted in rats to determine triethylene glycol toxicity showed in general, that the chemical was either without any adverse effects or produced toxicities only at doses at or greater than the limit doses established for EPA guideline test requirements. Triethylene glycol administered in the drinking water to rats at concentrations of 3% and 5% by volume for 30 days showed signs of toxicity (weight loss, alopecia and poor grooming) at the lower concentration with one animal dying on day 25 of the study. All rats in the 3% test group survived to study completion with no signs of toxicities.[12] In a 14-day oral toxicity study, Fischer 344 rats receiving triethylene glycol in the feed (doses equivalent to 1132, 2311 or 3916 mg/kg/day for males and 1177, 2411 or 6209 mg/kg/day for females) showed only changes in urinalysis (increased urine volume, decreased urine pH, and decreased urine triple phosphate crystals) at the highest respective doses tested in male and female rats.[13] In a third oral toxicity study conducted for 90-days in rats, triethylene glycol was administered in the diet at doses of 748, 1522 or 3849 mg/kg/day (males), and 848, 1699 or 4360 mg/kg (females). Although toxicities were noted at the high dose in male and female rats (decreases in body weight, slight decreases in hemoglobin and hematocrit, slight increases in mean corpuscular volume, and increased relative kidney and brain weights), these effects were noted at dose levels that exceed the established limit dose of 1000 mg/kg/day for such studies.[14]

In a 21-day dermal toxicity study, there was no evidence of dermal or systemic toxicity from repeated dermal applications of 2ml (approximately 600 mg/kg) triethylene glycol applied to the skin of rabbits. These results are supported by triethylene glycols' low dermal irritancy a negative response as a skin sensitizer. [15, 16]

Sprague-Dawley rats exposed (whole body) to triethylene glycol in an aerosol inhalation study at concentrations of 494, 2011, or 4842 mg/m^3 (0.5, 2.0, or 5.0 mg/L/day), for six hours a day, nine times over a two-week period showed the following toxicities at the highest concentration level tested: ataxia, prostration, unkept fur, labored respiration (males only), ocular discharge, swollen periocular tissue, perinasal and perioral encrustation, blepharospasm and reduced body weight Necropies revealed hyperinflation of the lungs, ocular opacity, congestion and hemorrhage in many organs and tissues (pituitary gland, brain, nasal mucosa, kidney, thymus and lungs). All of the rats in the high dose group died or were sacrificed moribund by day 5 of the study. Clinical signs of toxicity observed at the low- and mid-dose of 0.5 and 2.0 mg/L/day, respectively, were limited to swollen periocular tissues and perinasal encrustations. Treatment-related changes in organ weights in mid-dose males included an increase in liver and kidney weights relative to body weight; mid-dose females showed increases in absolute and relative (to body and brain weights) liver and kidney weights. Statistically significant clinical chemistry findings for males treated with 2.0 mg/L/day triethylene glycol included an increase in ALT activity and a decrease in serum creatinine levels. Mid-dose females showed increases in urea nitrogen, inorganic phosphorus, ALT and ALK activity, and decreases in glucose, creatinine, and chloride. However, the changes in organ weights and clinical chemistry findings were not correlated with any histopathological observations. [17]

Rats exposed to the test material via a whole-body inhalation protocol are also receiving the chemical via the oral and dermal routes. These additional routes of exposure may have increased the total dose received and contributed to the toxicities observed in the whole-body exposure inhalation study. Therefore, a second study was conducted using a nose-only exposure for 6 hours a day, 9 consecutive days. In this second inhalation toxicity study, mean exposure concentrations of 102, 517, or 1036 mg/m^3 (approximately 0.1, 0.5, 1.0 mg/L/day) triethylene glycol produced no treatment-related toxicities at any dose tested. [18]

Monkeys exposed by inhalation to approximately 1 ppm vapor from two weeks to 13 months and human volunteers exposed to air saturated with vapor (approximately 0.5 to 1 ppm) showed no adverse reactions or histopathological changes suggestive of toxicity from prolonged exposure to triethylene glycol. [19]

Dogs given daily intravenous injections (0.1 or 0.5 ml/kg) of triethylene glycol for four weeks showed no mortality or toxicity with the exception of flattened epithelial cells in the urine and phlebitis at the site of injection. [20]

Chronic Toxicity and Carcinogenicity

Published literature sources examining the chronic toxicity and carcinogenic potential of triethylene glycol have shown the chemical to be non toxic/negative in rodent species.

In a 12 month study, monkeys receiving triethylene glycol (0.25 mL to 0.5 mL) orally in egg nog (approximately 50 to 100 times the quantity an animal could absorb by breathing air saturated with glycol) were without any adverse effects in physiological functions or organ histopathology. [19]

Triethylene glycol administered in feed at levels of 0, 1, 2 or 4% to Osborn-Mendel rats for 2 years showed that the body weight gains, hematological parameters and clinical chemistries were not affected by treatment. Under the conditions of this study, triethylene glycol was not carcinogenic in rats. The dosages tested in rats are equivalent to as much as 3 to 4 g/kg/day which are well above the upper limit dose of 1 g/kg/day (1000 mg/kg/day) for testing pesticides via the oral route in subchronic and chronic toxicity studies. [21]

Mutagenicity

Triethylene glycol was tested for mutagenic or genotoxic potential and found to be negative in a battery of studies: a bacterial gene mutation assay using *Salmonela typhimurium*, an *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. [22 -25]

Dermal Absorption

No studies have been reported dealing with the skin absorption of triethylene glycol.

Although it is possible that, under conditions of very severe prolonged exposures to this chemical, absorption through the skin, it is doubtful any appreciable systemic/dermal injury would occur because triethylene glycol has (1) a low order of dermal irritancy, (2) is not a skin sensitizer, and (3) showed no evidence of dermal or systemic toxicity following repeated dermal applications of 2ml (approximately 600 mg/kg) triethylene glycol applied to the skin of rabbits in a 21-day dermal toxicity study.

Metabolism and Excretion

The fate of ^{14}C-labeled triethylene glycol in rats and of unlabeled material in rabbits was recently studied. Following oral dosing, the rat and rabbit excreted most of the triethylene glycol in both unchanged and/or oxidized forms (mono- and dicarboxylic acid derivatives of triethylene glycol). In rabbits dosed with 200 or 2000 mg/kg triethylene glycol respectively excreted 34.3% or 28%, of the administered dose in the urine as unchanged triethylene glycol and 35.2% as a hydroxyacid form of this chemical. In the studies with rats, little if any C^{14}-oxalate or C^{14}-triethylene glycol in conjugated form was found in the urine. Trace amounts of orally administered ^{14}C triethylene glycol were excreted in expired air as carbon dioxide (<1%) and in detectable amounts in feces (2 to 5 %). The total elimination of radioactivity (urine, feces and CO_2) during the five day period following an oral dose of labeled compound (22.5 mg) ranged from 91 to 98%. The majority of the radioactivity appeared in the urine. [26]

Developmental and Reproductive Toxicity

Triethylene glycol was administered orally at doses of 0, 0.5, 5.6, and 11.27 g/kg/day in timed pregnant CD-1 mice from gestation days 6 through 15. There were no treatment related maternal deaths and no abortions. Hyperactivity and rapid respiration were observed at the highest dose level. No effects were observed on maternal weight gain or food consumption at any dose level. Pregnancy outcome was unaffected at any dose level tested. There were no treatment-related effects on external or visceral malformations in offspring. Some evidence of delayed ossification was observed at the high dose level. [27]

In a second study, pregnant Sprague-Dawley rats were administered triethylene glycol by gavage on gestation days 6 through 15 at dose levels of 0, 1.0, 5.6, and 11.27 g/kg/day. There were no effects on maternal mortality and there were no abortions. Clinical toxicity was observed in maternal rats at the high dose and consisted of audible respiration, periocular encrustation, and perioral wetness. Decreased body weight and food consumption was observed in maternal rats at the 5.6 g/kg/day dose. No effects were observed at the 1.0 g/kg/day dose. In offspring, mean fetal body weight was decreased at the 11.27 g/kg/day dose level, but there were no treatment-related increases in external, visceral or skeletal malformations. [28]

Published literature examined the effect of triethylene glycol on reproduction in Swiss CD-1 mice. Doses of 0, 0.3, 1.5, and 3% were administered in drinking water using a continuous breeding protocol. No effects on reproductive function were observed at any dose level tested (up to the high dose of 6.78 g/kg) including sperm concentration, morphology, and motility. Reduced

pup weight was observed at the 1.5 and 3% doses of triethylene glycol. [29, 30]

In a study submitted to the Agency, rats were exposed to an atmosphere saturated with triethylene glycol (approx. 1 ppm) for 12-18 months with no adverse reproductive effects noted.[19, 31]

The available developmental and reproductive studies conducted with triethylene glycol are from published sources or from studies submitted to the Office of Toxic Substances and do not report all the data that are normally reported under the OPPTS 870 toxicity test guidelines. However, it is apparent that the toxicities observed in these studies are consistently manifested only at doses of triethylene glycol that exceed the established limit doses for animal studies and are of a non-specific nature. Therefore, there is no concern for the developmental or reproductive toxicity of triethylene glycol.

Neurotoxicity

From the available repeat dose toxicity studies, there was no evidence of neurotoxicity of triethylene glycol, however, the toxicology data are inadequate to characterize repeated dose toxicity. Therefore, neurotoxicity testing could be required if additional data are needed for future uses of triethylene glycol.

4.1 *Incident Reports*

As early as 1943, interest in the toxicity of triethylene glycol when inhaled was initiated by the observation that triethylene glycol was an effective air sanitizer. During these early studies conducted on the effectiveness of triethylene glycol, numerous persons were exposed and according to these reports, none were adversely affected. In addition, human exposure in the occupational handling and use of triethylene glycol has been uneventful and without reported cases of any adverse effects.

However, numerous reports retrieved from the OPP Incident Data System, Poison Control Centers, California Department of Pesticide Regulation (1982-2003), National Pesticide Telecommunications Network (NPTN) and published reports in the scientific literature have been associated with exposure to end-use products containing triethylene glycol. Inhalation exposure is the primary exposure route in these reported cases followed by dermal exposure. Most of the incidences are related to inhalation irritation and/or allergic-type reaction. The reported symptoms include respiratory irritation, coughing, chest tightness, difficulty breathing, shortness of breath, and wheezing. However, all the reported incidences involve exposure to end-use products (residential use) with greater than 50% of these incidences documented during human safety testing of one specific air sanitizer product. In addition, there is no one incident reported that identifies triethylene glycol as the single chemical exposure; the other ingredients in the end-use products may be substances contributing to most or all of the symptoms reported.

4.2 *Dose Response Assessment*

On February 25, 2003, the Agency's Antimicrobials Division Toxicology Endpoint Selection Committee (ADTC) reevaluated the available Toxicology data for Triethylene glycol and discussed endpoint selection for use as appropriate in occupational/residential exposure risk assessments. The potential for increased susceptibility of infants and children from exposure to triethylene glycol was also evaluated by the committee in order to meet the statutory requirements of the Food Quality Protection Act (FQPA) of 1996.

In addition to the submitted mammalian toxicity data, study reports were obtained and reviewed from other sources: published studies from the scientific literature and study reports submitted to the Agency's Office of Toxic Substances.

The ADTC concluded that there were no endpoints of concern for oral, dermal or inhalation exposure to triethylene glycol based on the low toxicity profile from the available toxicology studies.

4.3 *Hazard-based Special FQPA Safety Factor(s) for Infants and Children*

Based on the data available for triethylene glycol, there is no pre- or post-natal evidence for increased susceptibility following exposure to this active ingredient. As there are no active food uses registered by the EPA for triethylene glycol, the Antimicrobials Division determined that the special 10x hazard-based safety factor under the FQPA is not applicable at this time. This issue can be revisited if food uses become active in the future.

5.0 EXPOSURE ASSESSMENT

5.1 Dietary Exposure

Dietary exposure could potentially occur from the use of triethylene glycol as a preservative in food packaging adhesives, and from its use as an inert ingredient in agricultural pesticide formulations. For such inert uses, the Agency has developed a screening-level assessment tool with highly conservative assumptions regarding exposure to a generic inert used in such a manner. In this model, the following assumptions are made: (1) actual crop-specific residue data for active ingredients can be used as surrogate data for inert ingredient residue level; (2) the inert ingredient is assumed to be used on all crops; (3) 100% of all crops are "treated" with the inert ingredient; and (4) no adjustment is made for the percentage of the inert in the formulation, application rate or multiple applications of different active ingredient formulations. The results of this modeling represent an upper-bound estimate of likely dietary exposure to an inert resulting from preharvest use. An estimated acute and chronic dietary exposure of less than 1 mg/kg/day is made from this model. This value is orders of magnitude below the levels at which effects are observed from exposure to triethylene glycol as noted in the hazard profile, and thus dietary exposure does not present any risk of concern.

5.2 Drinking Water Exposure

The estimated environmental concentrations of triethylene glycol from use as an active ingredient (indoor use) and from agricultural and non-agricultural (outdoor) inert uses in surface water would not likely exceed a peak (24-hour time averaged) concentration of 885 ppb or an annual average (single year) concentration of 29 ppb. Estimated concentrations in ground water would not likely exceed 106 ppb. Estimated exposures from indoor use of triethylene glycol as the active ingredient and/or as an inert ingredient are unlikely to result in surface water concentrations greater than those from outdoor uses. The estimated dose from the highest estimated environmental concentration of 885 ppb would be approximately 0.025 mg/kg/day, an intake that is orders of magnitude below the level at which effects are observed from exposure to triethylene glycol. Thus, estimated concentrations in drinking water do not present any risks of concern.

5.3 Occupational and Residential Exposure

The occupational and residential exposure assessment for triethylene glycol addresses potential exposures and risks to humans who may be exposed in "occupational settings" and the general population in "residential settings." An occupational and/or residential exposure risk assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For triethylene glycol there is potential for exposure, however, there are no toxicological endpoints of concern, according to a review of the available toxicity data by the Antimicrobials Division Toxicology Endpoint Selection Committee (ADTC Report, 11/21,05).

Triethylene glycol is currently used in two applications: air sanitizer/hospital disinfectants and pest control on caged birds. Currently, triethylene glycol is only formulated as a pressurized liquid and is used only in applications where the risk of incidental ingestion may be considered minimal.

The potential handler scenarios identified are illustrated in Table 4. These scenarios were selected based on examination of product labels. Because air disinfectants may be applied in a wide variety of rooms, the list of possible application scenarios is extensive.

TABLE 4. Potential Handler Scenarios

Antimicrobial Category	Scenario
Commercial, institutional and industrial premises and equipment	• Spraying disinfectant in rooms of institutions, offices, schools, motels, hotels, etc.
Residential and public access premises	• Spraying disinfectant in rooms such as lobbies, theaters, reception rooms, sleeping rooms, bathrooms, etc.

Medical premises and equipment	• Spraying disinfectant on surfaces in hospitals and nursing homes. • Spraying disinfectant in hospital rooms.

No chemical-specific handler data were submitted to estimate the potential exposures associated with these uses of triethylene glycol (nor are they required at this time). Specifically, exposure data associated with spraying an aerosol can indoors, away from any surfaces (i.e., air sanitizer), or with spraying pets, are unavailable. However, similar exposures associated with spraying surfaces, such as crack and crevice treatments, are available from data provided by the Chemical Manufacturers Association (CMA) Antimicrobial Assessment Study (EPA, 1999) and the Pesticide Handlers Exposure Database (PHED). The PHED exposure data for aerosol can spraying is deemed more appropriate than the CMA data (e.g., more replicates, better analytical recovery values, etc). Application rates are difficult to assess for triethylene glycol because not enough information is provided on product labels. For spraying an aerosol in the air, most labels did not specify the quantity of product that should be used for a given room size, but rather state the length of time the aerosol should be sprayed for a given room size. For spraying surfaces, none of the labels provided enough information to calculate an application rate, due to the lack of data such as the volume of room air and the counter top/floor surface area.

In addition to potential dermal and inhalation handler exposure, there is the potential for post-application exposure to individuals reentering treated rooms and/or contacting sprayed surfaces. OPPT/EETD has developed a model, EFAST (Exposure and Fate Assessment Screening Tool), to estimate air concentrations. More information and access to the EFAST model is available at http://www.epa.gov/opptintr/exposurel.htm. In summary, EFAST bases its estimates on physical/chemical properties. Modeled results using the aerosol paint scenario in EFAST and a vapor pressure of 0.00132 mmHg at 250 degrees Celsius indicate a screening-level, high- end, peak concentration of 8.54 mg/^{M3}. No estimates of spray deposition on surfaces are available to estimate potential dermal contact.

Based on the lack of toxicological concerns for triethylene glycol, a quantitative risk assessment is not necessary at this time. If inhalation toxicological endpoints are identified in the future, a screening-level occupational and/or residential inhalation exposure estimate is available using EFAST. If dermal toxicological endpoints are identified in the future, potential dermal exposure estimates from treated surfaces will need to be developed.

6.0 ECOLOGICAL TOXICITY/ENVIRONMENTAL FATE

Ecological Toxicity

As a result of the Phase IV review of triethylene glycol for reregistration under FIFRA, ecological effects data requirements were waived due to its intended use as an indoor microbiocide, high volatility, and known low toxicity (it is a preferred solvent for aquatic organism toxicity tests). Data obtained from published studies provide additional confirmation of

the low toxicity of the compound to fish and aquatic invertebrates (Table 5).

TABLE 5. Ecotoxicity of Triethylene Glycol

Species	Percent Active Ingredient	Test Type	Toxicity	Reference
Mysid (*Mysidopsis bahia)*	99.9	96-hour static acute	LC50 = 11,000 ppm	MRID #40228401 (Mayer, 1986) [32]
Sheepshead minnow (*Cyprinodon variegatus*)	99.9	96-hour static acute	LC50 = 48,000 ppm	MRID #40228401 (Mayer, 1986) [32]
Bluegill sunfish (*Lepomis macrochirus*)	unknown	96 hour static acute	LC50 > 10,000 ppm	Verschuren, 1983 [33]
Menidia beryllina	unknown	96 hour static	LC50 > 10,000 ppm	Verschuren, 1983 [33]
Fathead minnow (*Pimephales promelas*)	unknown	96 hour flow-through	LC 50 59,900 - 77,400 ppm	Geiger et al., 1988 [34]

Environmental Fate/Surface and Ground Water

OPP has no data base on environmental fate studies for triethylene glycol use as air sanitizers. Triethylene glycol is an aliphatic hydroxy chemical and although a hydrolysis study is the only environmental fate data required for chemicals with an indoor use pattern, the Agency granted a data waiver for this study during the Phase IV review of triethylene glycol based on the fact that this chemical does not contain any hydrolyzable hydrogen. For the reregistration eligibility decision (RED) process, the Agency has relied on readily available open literature data that characterizes the fate properties of triethylene glycol.

Based on a review of the information, triethylene glycol is miscible in water, mobile in soils, stable to abiotic degradation hydrolysis and soil and aquatic photolysis. Biodegradation is expected to proceed rapidly in surface waters based on a number of River Dye-away tests (complete mineralization between 7 and 11 days) and will degrade in soils in days (primary degradation) to weeks (complete mineralization) based sludge innoculum studies and predictions of ready biodegradability. The use of sludge innoculum data as a surrogate for terrestrial soil metabolism is subject to considerable uncertainty because sludge innoculums tend to be acclimated to the introduction of organic substances, more so than soils, and the biomass on a per volume basis tends to be greater. In light of these uncertainties, data reported for the mineralization of triethylene glycol in sludge innoculums were assigned an uncertainty factor of 3 times the estimated value to account for media differences. This adjustment factor, in conjunction with the use of a mineralization time rather than a half-life, is likely to bound the upper-end of the potential soil half-life, thus maintaining a reasonble yet conservative assessment.[8, 35]

Application rates were not available for indoor or outdoor uses, although percentages of formulations were. To assess the potential concentrations of triethylene glycol in surface and ground water, application rates of 1 lb/acre and 10 lbs/acre were assessed. Through experience, the Agency's Lower Toxicity Pesticide Chemical FOCUS Group (formerly the Inerts FOCUS Group) has concluded that with rare exceptions, inert compounds are not applied at rates greater than 10 pounds per acre. Therefore, assessing triethylene glycol at a maximum of 10 lbs/acre is considered a reasonable high-end exposure scenario. Aerial application of triethylene glycol is assumed although it is unlikely to be used in spray applications where a ultra fine droplet size is used due to its vapor pressure.

Surface Water and Ground Water

The FQPA Index Reservoir Screening Tool (FIRST) was used to estimate concentrations of triethylene glycol at the intake of a community water system. SCI-GROW was used to estimate concentrations of this chemical in shallow groundwater drinking water sources. The environmental fate inputs for triethylene glycol are presented in Table 6. The half-life of triethylene glycol on soils was assumed to be equal to the highest observed time for mineralization (95 % of total applied) of approximately 28 days. In addition, an uncertainty factor of 3 times the mineralization time was applied to account for the differences in media (soils vs. sludge). The aerobic aquatic metabolism halflife was modeled at 7 and 11 days. These times are equivalent to

the time to complete mineralization rather than a true half-life which will introduce additional conservatism in the assessment. Raw data were not available to determine an actual half-life from the River Dye-away studies.

Table 6. Environmental Fate Input Parameters				
Parameter	**Scenario 1**	**Scenario 2**	**Scenario 3**	**Scenario 4**
Application Rate/Number	1/1	1/1	10/1	10/1
Soil Koc	10	10	10	10
Water Solubility (mg/L)	100,000	100,000	100,000	100,000
Hydrolysis Half-life (days)	stable	stable	stable	stable
Photolysis half-life (days)	stable	stable	stable	stable
Soil Metabolism Half-life (days)	84	84	84	84
Aerobic Aquatic Metabolism Half-life (days)	11	7	11	7

The estimated environmental concentrations of triethylene glycol from use as an active ingredient (indoor use) and from agricultural and non-agricultural (outdoor) uses are presented in Table 7. Based on a series of "what if" approaches, the estimated environmental concentrations of triethylene glycol from use as an active ingredient (indoor use) and from agricultural and non-agricultural (outdoor) uses in surface water would not likely exceed a peak (24-hour time averaged) concentration of 885 ppb or an annual average (single year) concentration of 29 ppb. Estimated concentrations in ground water would not likely exceed 106 ppb. Estimated exposures from indoor use of triethylene glycol as the active ingredient and/or as an inert ingredient are unlikely to result in surface water concentrations greater those from outdoor uses. Releases to wastewater treatment plants are expected to be minimally removed because of the lack of residence time (hours). Predicted removal efficiencies do not exceed 10 percent of the amount released.

Table 7. FIRST and SCI-GROW Estimated Environmental Concentrations (ppb)					
Model		**Scenario 1**	**Scenario 2**	**Scenario 3**	**Scenario 4**
FIRST	Peak	88.5	88	885	880
	Annual Average	2.9	1.9	29	19
SCI-GROW		10.6	10.6	106	106

7.0 AGGREGATE EXPOSURE

In examining aggregate exposure, FFDCA section 408 (b)(2)(d)(vi) stipulates that "when establishing, modifying, leaving in effect or revoking a tolerance or exemption for a pesticide

chemical residue, that EPA consider available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue" in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns or buildings (residential and other indoor uses).

Over 1 million pounds of triethylene glycol are either produced or imported per year (according to OPPTS, triethylene glycol is categorized as an HPV chemical and by definition is produced world-wide in quantities greater than one million pounds). Some of this production is used as a chemical intermediate, in the production of other chemicals. Triethylene glycol has been approved by the Food and Drug Administration for use as an indirect food additive as a component of adhesives. According to 21 CFR 175.105, triethylene glycol can be a component of an adhesive used as part of "articles intended for use in packaging, transporting or holding food."

The Agency has developed screening-level models to estimate exposures that could occur as a result of the use of an inert ingredient such as triethylene glycol on agricultural crops. These models make a number of highly conservative assumptions that deliberately over-estimate exposure in the diet, drinking water, and from residential use (Table 8).

Table 8. Screening-Level Model Estimates of Exposure to Triethylene Glycol

Type of Exposure	**Exposure Level**
Dietary - Food (as a result of application to crops)	acute exposure: less than 1 mg/kg/day at 95th percentile chronic exposure: less than 1 mg/kg/day
Dietary - Drinking Water	acute exposure: much less than 1 mg/kg/day chronic exposure: much less than 1 mg/kg/day
Residential (as a result of using a cleaning product)	approximately 6 mg/kg/day
Residential (as a result of using a laundry detergent)	approximately 1 mg/kg/day
Residential (as a result of application to a lawn)	less than 1 mg/kg/day

With one exception, all of the screening-level exposure estimates noted above are in the range of 1 mg/kg/day or less. Examination of the hazard profile for triethylene glycol shows that levels at which adverse effects are observed occur in excess of 1000 mg/kg/day by the oral and dermal routes, and in excess of 1 mg/L by the inhalation route. Considering the worst-case aggregate exposures that could occur from the inert use of triethylene glycol as well as the air sanitizer use,

the total human exposure is orders of magnitude below any dose of triethylene glycol that has been shown to cause an adverse effect**.**

Determination of Safety

Based on its review and evaluation of the available information, EPA concludes that there is a reasonable certainty that no harm will result to the general population, including infants and children, from aggregate exposure to residues of triethylene glycol, including all active and inert uses in pesticide products.

7.1 Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or such other endocrine effect..." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing triethylene glycol for endocrine effects may be required.

7.2 Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify or revoke a tolerance, 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."

EPA does not have, at this time, available data to determine whether triethylene glycol has a common mechanism of toxicity with other substances. 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 as to triethylene glycol. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at Http://www.epa.gov/pesticides/cummulativel.htm.

8.0 SUMMARY OF RISK ASSESSMENT FINDINGS

From the available animal studies and other data, EPA has concluded that triethylene glycol exhibits low toxicity and exposures to triethylene glycol used as both an active or inert present a reasonable certainty that no harm will result from exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other types of exposures for which there is reliable information.

The Agency notes that triethylene glycol is included on the Agency's list of chemicals included in the High Production Volume (HPV) Challenge Program. HPV chemicals are those that are manufactured or imported into the United States in volumes greater than one million pounds per year. There are approximately 3,000 HPV chemicals that are produced or imported into the United States. The HPV Challenge Program is a voluntary partnership between industry, environmental groups, and the EPA that invites chemical manufacturers and importers to provide basic hazard data on the HPV chemicals they produce/import. The goal of this program is to facilitate the public's right-to-know about the potential hazards of chemicals found in their environment, their homes, their workplace, and in consumer products.

The Agency received a full commitment from two companies to sponsor triethylene glycol as part of the Agency's HPV Challenge Program.

Based on toxicity data already submitted on triethylene glycol, and the completeness of the toxicity data base (including subchronic, chronic, reproduction, teratology, and mutagenicity studies), the Agency feels confident in proceeding with this reregistration eligibility decision/tolerance reassessment decision. Any submission of data by current or future sponsors of triethylene glycol as part of the HPV Challenge Program may, in the future, be used by the Office of Pesticide Programs to revise or update their tolerance reassessment decision for triethylene glycol as deemed necessary and appropriate.

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10.0 WEBSITES

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EFAST Model located at Http://www.epa.gov/oppt/exposure/docs/episuitedl.htm.

Environmental Fate Literature located at Http://www.epa.gov/oppt/exposure/docs/episuitedl.htm.

Cumulative Risk Assessment Policy located at Http://www.epa.gov/pesticides/cummulativel.htm.