United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(7510P)

EPA 739-RO-8009
September 2008

Reregistration Eligibility Decision for Triclosan

List B

Case No. 2340

Reregistration Eligibility Decision (RED) Document

for

Triclosan

Approved by: _____

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Director
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Date: _____

September 18, 2008

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EXAMS	Exposure Analysis Modeling System
EUP	End-Use Product
FCID	Food Commodity Intake Database
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
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
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
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
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for 5-Chloro-2-(2,4-dichlorophenoxy)phenol (triclosan) and is issuing its reregistration eligibility and risk management decisions. The risk assessments, which are summarized in this document, are based on review of registrant-submitted data supporting the use patterns of currently registered products, citations from the open literature, and additional information received through the public docket. The risk assessments have been revised, as needed, according to information received since they were first made available to the public in May 2008. After considering the risk assessments and risk mitigation options, the Agency developed its reregistration eligibility and risk management decisions for uses of triclosan. As a result of this review, EPA has determined that all uses of triclosan are eligible for reregistration, with the exception of the paint use, provided that the risk mitigation and data requirements outlined in this document are fully implemented. The reregistration eligibility decision is discussed fully in this document. The Agency is aware that research is ongoing regarding triclosan. The outcomes of this further research may require the Agency to revisit this decision in the future. Further, given the rapidly developing scientific database for triclosan, the Agency intends to accelerate the schedule for the registration review process for this chemical. Currently, the Agency intends to begin that process in 2013, ten years earlier than originally planned.

I. Introduction

This document is the Environmental Protection Agency's (EPA or "the Agency") Reregistration Eligibility Decision (RED) for all currently registered uses of 5-Chloro-2-(2,4-dichlorophenoxy)phenol (triclosan). This document also summarizes the human health and environmental exposure and associated risks used to make the reregistration eligibility decision.

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 (EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of 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.

The Agency made its reregistration eligibility decision for triclosan 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 triclosan, with the exception of the use as a materials preservative in paint (which has been requested to be voluntarily cancelled by the registrants), are eligible for reregistration provided the conditions and requirements for reregistration identified in this reregistration eligibility decision (RED) are implemented.

This document consists of six sections: Section I contains the regulatory framework for reregistration reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and ecological risk assessments; Section IV presents the Agency's reregistration eligibility and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents, and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov under docket number EPA-HQ-OPP-2007-0513.

II. Chemical Overview

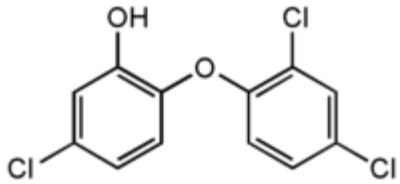
A. Regulatory History

Triclosan is regulated by both the U.S. EPA and the U.S. Food and Drug Administration (FDA). The EPA regulates the antimicrobial uses of triclosan when used as a bacteriostat, fungistat, mildewstat, and deodorizer. EPA-registered products containing triclosan as the active ingredient are formulated as ready-to-use, pelleted/tableted, emulsifiable concentrate, soluble concentrate, and impregnated materials. Triclosan is used in commercial, institutional and industrial premises and equipment; residential and public access premises; and as a material preservative. Commercial, institutional and industrial premises and equipment uses include conveyor belts, fire hoses, dye bath vats and ice making equipment. As a material preservative, triclosan is used in many products including adhesives, fabrics, vinyl, plastics (toys, toothbrushes), polyethylene, polyurethane, polypropylene, floor wax emulsions, textiles (footwear, clothing), caulking compounds, sealants, rubber, and latex paints. There are a multitude of residential and public access premises uses including direction application to HVAC coils (limited to commercial applicators), and use as a materials preservative in toys, paints, mattresses, clothing, brooms, mulch, floors, shower curtains, awnings, tents, toilet bowls, urinals, garbage cans, refuse container liners, insulation, concrete mixtures, grouts, and upholstery fabrics. The FDA-regulated uses include hand soaps, toothpaste, deodorants, laundry detergent, fabric softeners, facial tissues, antiseptics for wound care, and medical devices.

No direct food use is associated with triclosan; therefore, no tolerance or tolerance exemption has been established. However, dietary exposure and risk were assessed for the indirect food uses of triclosan involving pulp and paper use, ice-making equipment, adhesives, cutting boards, conveyor belts, and counter top use.

B. Chemical Identification

Triclosan Molecular Structure:



Common Name:	2,4,4'-Trichloro-2'-hydroxydiphenyl ether Phenol, 5-chloro-2-(2,4-dichlorophenoxy)- 5-Chloro-2-(2,4-dichlorophenoxy)phenol Irgasan DP-300R Irgaguard B1000 VIV-20
OPP Chemical Codes:	054901

CAS Registry No.: 3380-34-5

Case Number: 2340

Molecular Formula: $C_{12}H_7C_{l3}0_2$

Chemical Characteristics for Technical Grade Active Triclosan:

Molecular Weight	289.541
Color	White crystals
Physical State	White crystalline powder
Specific Gravity	1.55 x 10^3 kg/m^3 at 22˚C
Dissociation Constant	pK_a=8.14 at 20°C
pH	N/A
Stability	Stable at normal conditions
Melting Point	56.5 ^{o} C
Boiling Point	N/A
Water Solubility	0.012 g/l at 20˚C
Octanol-Water Partition constant ($LogK_{OW}$)	4.8 at 25˚C
Vapor Pressure	5.2E-6 mm Hg at 25˚C 2.2E-6 mm Hg at 20˚C

Manufacturers: Ciba Corporation and Har-Met International, Inc.

Highest Percent of Active Ingredient: 99%

Formulation Types Registered: ready-to-use, pelleted/tableted, emulsifiable concentrate, soluble concentrate, and impregnated materials

C. Use and Usage

Triclosan was first registered by the EPA in 1969, and currently there are 20 antimicrobial registrations. A detailed table of the uses of triclosan eligible for reregistration can be found in Appendix A.

Type of Pesticide: Fungicide, Bacteriostat

Use Sites for EPA Registrations:

Commercial, institutional and industrial premises and equipment: conveyor belts, fire hoses, dye bath vats and ice making equipment.

As a material preservative: adhesives, fabrics, vinyl, plastics (toys, toothbrushes), polyethylene, polyurethane, polypropylene, floor wax emulsions, textiles (footwear, clothing), caulking compounds, sealants, rubber, and latex paints.

Residential and public access premises: direction application to HVAC coils (limited to commercial applicators), use as a materials preservative in toys, paints, mattresses, clothing, brooms, mulch, floors, shower curtains, awnings, tents, toilet bowls, urinals, garbage cans, refuse container liners, insulation, concrete mixtures, grouts, and upholstery fabrics.

Target Pests: Bacteria, fungi

Formulations: EPA-registered products containing triclosan as the active ingredient are formulated as ready-to-use, pelleted/tableted, emulsifiable concentrate, soluble concentrate, and impregnated materials.

Application Methods: Direct application of triclosan in a manufacturing setting via closed system, open pour or metered pump; direct application to HVAC coils (spray); residential and occupational handler painting using brush or airless sprayer (using end-use product where triclosan is used as the materials preservative)

III. Summary of Triclosan Risk Assessments

The purpose of this section is to summarize EPA's human health and ecological risk conclusions for triclosan to help the reader better understand EPA's risk management decisions. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for triclosan. The full risk assessments and related supporting documents are available at http://www.regulations.gov under docket number EPA-HQ-OPP-2007-0513. Hard copies of these documents may be found in the OPP public docket which is located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m.to 4:00 p.m.

EPA developed this RED for triclosan through a modified, 4–Phase public participation process. The Agency uses public participation processes to involve the public in developing pesticide reregistration decisions. EPA released its preliminary risk assessments for 60-day public comment in May 2008. Comments were incorporated into the final risk assessments which were used to make this reregistration eligibility decision.

The Agency is aware of recent research conducted by the Office of Research and Development on the effects of triclosan on thyroid homeostasis in the rat (US EPA, 2008). These data were considered in selection of the incidental oral endpoint, but the current endpoint was retained, as further investigation is needed on the effects of triclosan on the thyroid. The Agency will continue to monitor the toxicity profile of triclosan and will amend the assessment as needed.

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

A. Human Health Risk Assessment

EPA has conducted a human health risk assessment for triclosan to support the reregistration eligibility decision. EPA evaluated the submitted toxicology, product and residue chemistry, and occupational/residential exposure studies as well as available open literature and determined that the data are adequate to support this reregistration eligibility decision. A summary of the human health risk assessment findings and conclusions is provided below.

1. Toxicity Profile

The toxicological database for triclosan is adequate to support a reregistration eligibility decision. Major features of the toxicology profile are presented below. Detailed information is available in the *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document,* dated August 29, 2008.

a. Acute Toxicity Profile

Triclosan has low acute toxicity via the oral and dermal routes (Category IV) and moderate acute toxicity via the inhalation route (Category II). It is moderately irritating to the eye (Category II), is a moderate to mild dermal irritant (Category III), and not a skin sensitizer. Table 1 presents the acute toxicity profile for triclosan.

Table 1. Acute Toxicity Profile for Triclosan

Guideline Number	Study Type/ Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral- Rat Triclosan (99.7% a.i.)	43206901	LD_{50}: >5000 mg/kg	IV
870.1200 (§81-2)	Acute Dermal- Rabbit Triclosan (97% a.i.)	94044	LD_{50}: >9300 mg/kg	IV
870.1300 (§81-3)	Acute Inhalation- Rat Triclosan (100.5% a.i.)	42306902, 43310501	LC_{50}: >0.15 mg/L	II
870.2400 (§81-4)	Primary Eye Irritation- Rabbit Triclosan (97% a.i.)	94045	moderately irritating	II
870.2500 (§81-5)	Primary Dermal Irritation- Rabbit Triclosan (% a.i. not provided)	42306903	PII: 3.5 at 72 hours	III
870.2600 (§81-6)	Dermal Sensitization- Guinea Pig Triclosan (99.7% a.i.)	43206502	Not a Sensitizer	N/A

b. Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment are presented in Table 2. The uncertainty and safety factors used to account for interspecies extrapolation, intraspecies variability, and for completeness of the database are also presented. The Agency is aware of recent research conducted by the Office of Research and Development on the effects of triclosan on thyroid homeostasis in the rat (US EPA, 2008). These data were considered in selection of the incidental oral endpoint, but the current endpoint was retained, as further investigation is needed on the effects of triclosan on the thyroid. The Agency will continue to monitor the toxicity profile of triclosan and will amend the assessment as needed.

Table 2. Summary of Triclosan Toxicological Endpoints			
Exposure Scenario	**Dose Used in Risk Assessment**	**Uncertainty factors for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (general population)	NOAEL = 30 mg/kg **arid** = 0.3 mg/kg/day	Interspecies = 10x Intraspecies = 10x DBSS = 1x UF = 100	Chronic Toxicity study in Baboons MRID 133230 LOAEL = 100 mg/kg/day, based on clinical signs of toxicity such as vomiting, failure to eat and diarrhea
Chronic Dietary (all populations)	NOAEL = 30 mg/kg **crud** = 0.3 mg/kg/day	Interspecies = 10x Intraspecies = 10x DBSS = 1x UF = 100	Chronic Toxicity study in Baboons MRID 133230 LOAEL = 100 mg/kg/day, based on clinical signs of toxicity such as vomiting, failure to eat and diarrhea
Short-Term/ Intermediate-Term Incidental Oral (1-30 days; 30 days- 6 months)	NOAEL = 30 mg/kg	Interspecies = 10x Intraspecies = 10x DBSS = 1x UF = 100	Chronic Toxicity study in Baboons MRID 133230 LOAEL = 100 mg/kg/day, based on clinical signs of toxicity
Dermal (short-term)	NOAEL = 0.6 mg/animal (100 $\mu g/cm^2$)	Interspecies = 3x Intraspecies = 3x DBSS =1x MOE = 10	14-day dermal toxicity study in the mouse MRID 44389708 LOAEL = 1.5 mg/kg/day, based on treatment-related dermal irritation at the treatment site and on increased liver weights
Dermal (intermediate term)	NOAEL = 40 mg/kg	Interspecies = 10x Intraspecies = 10x DBSS =1x MOE = 100	90-day Dermal Toxicity in Rats MRID 43328001 LOAEL = 80 mg/kg/day, based on increased incidence occult blood in the urine.
Dermal (long-term)	NOAEL = 40 mg/kg	Interspecies = 10x Intraspecies = 10x DBSS =3x (lack of chronic dermal study) MOE = 300	90-day Dermal Toxicity in Rats MRID 43328001 LOAEL = 80 mg/kg/day, based on increased incidence occult blood in the urine.

Table 2. Summary of Triclosan Toxicological Endpoints			
Exposure Scenario	**Dose Used in Risk Assessment**	**Uncertainty factors for Risk Assessment**	**Study and Toxicological Effects**
Inhalation (all durations)	LOAEL = 3.21 mg/kg/day	MOE = 1000 [a]	21-Day Inhalation Toxicity study in the rat MRID 0087996 LOAEL = 3.21 mg/kg/day [males], based on increased total leucocyte count and increased serum alkaline phosphatase
Cancer (oral)	In accordance with the *EPA Final Guidelines for Carcinogen Risk Assessment (March 29, 2005)*, the HED CARC classified triclosan as "Not Likely to be Carcinogenic to Humans".		

UF = uncertainty factor, DBSS = database uncertainty [special sensitivity] factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

[a]MOE of 1000 was applied to the inhalation endpoint. The inhalation toxicity study lacked sufficient data with which to convert the animal doses to human equivalent concentrations (HECs) in accordance with Agency policy. A LOAEL value was selected as the endpoint for inhalation risk assessment; therefore, the use of the LOAEL value from the animal study and uncertainty in determination of what the HEC would be warrants the MOE of 1000.

2. Dietary Exposure and Risk from Food and Drinking Water

Dietary exposure and risk were assessed for the indirect food uses of triclosan involving pulp and paper use, ice-making equipment, adhesives, cutting boards, conveyor belts, and counter top use. As no residue chemistry data were submitted to the Agency for triclosan, the standard methods developed by the FDA were used to estimate the potential migration of residues. A detailed explanation is found within the *Dietary Risk Assessment for Triclosan*, dated August 11, 2008. None of the individual scenarios for the various indirect food uses for triclosan presented risks of concern for either adults or children.

Exposures can occur where there is the possibility of indirect food migration (including paper/pulp use, use in ice-making equipment, adhesives, cutting boards, counter tops, and conveyer belts). The National Health and Nutrition Surveys (NHANES) are a series of U.S. national surveys of the health and nutrition status of the non-institutionalized civilian population conducted by the Centers for Disease Control and Prevention. The NHANES data are believed to be a more accurate predictor of aggregate exposure because not only are the data triclosan specific, they are also based on actual consumer use of the various triclosan products as they co-occur in practice (see the *Residential Post Application/Bystander Risk Summary* section of this RED document for a full explanation of the NHANES data). The NHANES data accounts for indirect dietary and water exposures more effectively than the use of standard models that the Agency normally would use to

estimate the potential migration of residues. We are presenting the dietary model results as additional information regarding the pathways of exposure.

EPA-registered products containing triclosan are largely used indoors as a materials preservative. However, there is potential for effluents from EPA-registered products containing this chemical to contact fresh water environments. Triclosan was detected in both raw and finished drinking water in Southern California at levels of 56 and 49 ng/L, respectively (Loraine and Pettigrove, 2006). Using the assumption of 2L consumption per day for adults, the intake of triclosan is estimated at 98 ng/person/day or 1.4 ng/kg/day for a 70 kg adult. Comparing this intake value to the selected reference dose for triclosan (0.3 mg/kg/day or 300,000 ng/kg/day), the intake of triclosan in drinking water using the measured value from Loraine and Pettigrove study does not present a risk of concern. Triclosan degrades with an average half-life value of 5.2 ± 1.7 days. Therefore, based on the EPA use patterns, and the relatively short half-life, the potential for effluents from EPA-registered products to impact drinking water sources is negligible. Therefore a quantitative drinking water assessment was not conducted. For additional information see the *Dietary Risk Assessment for Triclosan*, dated August 11, 2008.

Non-cancer dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose at or below which no unreasonable adverse health effects to any human population subgroup are expected to occur. This dietary level of concern is termed the population adjusted dose (PAD), which reflects the reference dose (RfD), either acute or chronic, adjusted for (divided by) any database uncertainty (special sensitivity) factor. In the case of triclosan, the special sensitivity factor is 1x (estimated risks that are less than 100% of the PAD are below EPA's level of concern). The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on a single day with no expected adverse health effect. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no expected adverse health effect.

Using conservative assumptions, the Agency estimated dietary exposure to triclosan when used in adhesives, pulp and paper, ice-making equipment, countertops and cutting boards and conveyer belts (see Table 3 below). Because the aPAD and cPAD are well below 100%, dietary exposure does not exceed the Agency's level of concern. For additional information on these calculations please see the *Dietary Risk Assessment for Triclosan*, dated August 11, 2008.

Table 3. Dietary Exposure to Triclosan

Use	**% aPAD (aPAD = 0.30 mg/kg/day)**	**% cPAD (cPAD = 0.30 mg/kg/day)**
Adhesive	Adult: 0.0003/0.30 x 100) = **0.10%**	Adult: 0.0003 mg/kg/day ⁄ 0.3 mg/kg/day x100 = **0.10%**
	Child: 0.0007/0.30 x100 = **0.23%**	Child: 0.0007 mg/kg/day ⁄ 0.30 mg/kg/day x 100 = **0.23 %**

Pulp and Paper	Adult: 0.00039 mg/kg/day / 0.30 mg/kg/day x 100 Adult: 0.00039 mg/kg/day/0.30 mg/kg/day x 100 = **0.13%** Child: 0.00092 mg/kg/day / 0.37 mg/kg/day = **0.30%**	Adult: 0.00039 mg/kg/day/0.30 mg/kg/day x 100 = **0.13%** Child: 0.00092 mg/kg/day / 0.037 mg/kg/day = **0.30%**
Ice-Making Equipment	Adult: 1.13 x10^{-8} mg/kg/day/ 0.30 mg/kg/day = 3.76 x 10^{-8} x 100 = **3.76 x 10^{-6} %** Child: 2.65 x 10^{-8} mg/kg/day /0.30 mg/kg/day = 8.83 x 10^{-8} x 100 = **8.83 x 10^{-6} %**	Adult: 1.13 x10^{-8} mg/kg/day/ 0.30 mg/kg/day = 3.76 x 10^{-8} x 100 = **3.76 x 10^{-6} %** Child: 2.65 x 10^{-8} mg/kg/day /0.30 mg/kg/day = 8.83 x 10^{-8} x 100 = **8.83 x 10^{-6} %**
Countertops and cutting boards	Adult: 0.0286 mg/kg/day/ 0.30 mg/**kg/day = 9.53%** Child: 0.1333 mg/kg/day/ 0.3 mg/kg/day x 100 **= 44.3%**	Adult: 0.0286 mg/kg/day/ 0.30 mg/**kg/day = 9.53%** Child: 0.1333 mg/kg/day/ 0.3 mg/kg/day x 100 **= 44.3%**
Conveyer Belt Use	Adult: 0.0000123 mg/kg/day/0.30 mg/kg/day x 100 = **0.041%** Child: 0.000057 mg/kg/day / 0.30 mg/kg/day x 100 = **0.019%**	Adult: 0.0000123 mg/kg/day/0.30 mg/kg/day x 100 = **0.041%** Child: 0.000057 mg/kg/day / 0.30 mg/kg/day x 100 = **0.019%**

3. Residential Exposure and Risk

To assess residential handler risks, the Agency used surrogate unit exposure data from the Chemical Manufacturers Association (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED) (the NHANES data most likely do not capture intermittent uses of triclosan such as home owners using paint that has been preserved with triclosan because the NHANES sampling is from a discrete sampling timeframe). Residential post-application/bystander exposures were assessed using the NHANES biological monitoring data from the general population for ages 6+ years old as well as bounding estimates for infant exposure using EPA's standard assumptions In addition, the post-application assessment looked at the potential for incidental dermal irritation as well as systemic dermal exposure as there is the potential for adults and children to contact impregnated textiles and fabrics such as clothing items and mattresses. Although

the contribution of dermal exposure to the aggregate exposure is represented in the NHANES data, a post-application screening-level clothing assessment to represent exposure to treated textiles and fabrics is provided. Infant-specific pathways of exposure were also assessed, as the NHANES data do not take into account the potential exposure pathways of triclosan-treated products for younger children such as putting objects and/or hands into their mouths.

There are no EPA-registered products containing triclosan that can be applied by a homeowner in a residential setting. However, triclosan can be used as an in-can preservative for latex paint, and articles treated with triclosan in an occupational setting also have the potential for post-application residential exposure (e.g. as a materials preservative in mattresses, clothing, tooth brush bristles, plastic toys, garbage bags, paper, playground equipment, sponges, furniture, footwear, etc.). Triclosan can also be used by service contractors to control, prevent, and inhibit the growth of fungi, mildew, mold, and bacteria on coils in residential heating, ventilating, and air conditioning (HVAC) systems.

Residential non-cancer risk estimates are typically 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 (MOE = dose ÷ exposure). Estimated MOEs are then compared to the "target MOE" which represents the dose selected for risk assessment and uncertainty factors (UF) applied to that dose (target MOE = dose × uncertainty factors). 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 within the same species). Additional uncertainty or safety factors may also be applied.

There is the potential for individuals in residential settings to be exposed to triclosan following application of products containing triclosan. Table 4 presents the representative scenarios used to estimate residential risk from products containing triclosan.

Table 4. Representative Uses Associated with Residential Exposure to Triclosan

Representative Use	Application Method	Example Registration Number	Application Rate
Paint (Latex)	• Brush and airless sprayer	42182-1	0.1 lb a.i./gallon [up to 1% product x 99% a.i. x 10 lb/gal paint density = 0.099 lb a.i./gallon of paint]
Textiles (exposures to treated articles are represented by exposure to mattress and clothing)	• N/A[a]	70404-5	Round to 2% a.i. in finished textiles and mattresses. (Rates range up to the finished product containing 2% formulated product by weight. Triclosan product contains 99% a.i..)

Table 4. Representative Uses Associated with Residential Exposure to Triclosan			
Representative Use	Application Method	Example Registration Number	Application Rate
Plastic (exposures to plastic treated articles are represented by plastic toys)	• N/A[a]	42182-1	0.5% a.i. (0.1% to 0.5% product x 99% a.i.)

(a) The handler's scenarios were not assessed because the products can only be applied occupationally

a. Residential Handler Risk Summary

Handler exposures were assessed for the in-can preservative use in paint. Dermal exposures for the short-term duration were not assessed because no systemic dermal toxicity was observed. Dermal irritation was observed in the toxicity study using a test substance containing 99 percent active ingredient (a.i.). Residential uses are at or below 1 to 2 percent a.i. are not expected to cause irritation. For additional information, please see the *Revised Triclosan Occupational and Residential Exposure Assessment*, dated September 8, 2008.

The estimated risk from exposure to triclosan in residential settings does not exceed the Agency's level of concern for inhalation during the paint brush application (MOE= 4,000; target MOE = 1000). However, the estimated risk from exposure to triclosan in residential settings is of concern during the airless sprayer application (MOE= 180; target MOE = 1000). Personal protective equipment (PPE) such as respirators is not a viable mitigation option for residential paint uses for an in-can preservative. Mitigating with PPE is only a viable option for pesticide-labeled products (i.e., a label is needed to inform workers to wear PPE). Therefore, the Agency can direct workers using pesticide-labeled products (concentrated form) at the manufacturing setting to wear PPE to mitigate dermal irritation. Conversely, for in-can material preservatives there is no pesticide label that goes with the preserved product to inform the workers/painters that PPE is needed (i.e., there is no pesticide label on a can of paint). However, a request has been received by the Agency from the registrants to voluntarily cancel the paint use (inclusive of stains and coatings). Once the action to terminate the paint use is completed, any risks associated with triclosan-treated paint will be mitigated. For additional information on how the residential assessment was conducted see the *Revised Triclosan Occupational and Residential Exposure Assessment*, dated September 8, 2008.

Table 5. Triclosan Short-Term Residential Handler Inhalation Exposures and MOEs						
Exposure Scenario Application Method	Application Method	Application Rate	Quantity Handled/ Treated per day	Unit Exposure (mg/lb a.i.)	Daily Dose (mg/kg/day) [c]	MOE [d] (Target MOE = 1000)
Painting	Paint brush	0.1 lb a.i./gal	2 gallons	0.28	0.0008	4,000
	Airless sprayer		15 gallons	0.83	0.018	**180**

a Application rates are the maximum application rates determined from EPA registered labels for triclosan.
b Amount handled per day values are estimates or label instructions.
c Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) x application rate (% a.i. weight or lb a.i./gal) x quantity treated (lb/day or gal/day) x absorption factor (1.0 for inhalation)]/ Body weight (70 kg for inhalation).
d MOE = LOAEL / Daily Dose. [Where short-term inhalation LOAEL = 50 mg/m^3 or a dose of 3.21 mg/kg/day]. Target MOE = 1000.

b. Residential Post Application/Bystander Risk Summary

For EPA-registered products, triclosan may be used as an active ingredient in textiles and fabrics (e.g., mattresses and clothing/bibs) and plastic products (e.g., toys, cutting boards, etc). Exposures can occur where there is the possibility of indirect food migration, including paper/pulp use, use in ice-making equipment, adhesives, cutting boards, counter tops, and conveyer belts. In addition to EPA-regulated uses, the residential post-application assessment also includes an aggregate assessment of the FDA uses such as toothpaste, hand soaps, and deodorants. The aggregate assessment includes both EPA- and FDA-registered uses because the biological monitoring methodology, NHANES, used to collect the samples from the general population does not allow for separation of the contribution of individual products to total exposure. Although the aggregate exposure/risk assessment using the NHANES data provides an encompassing review of all triclosan-treated products, it does not include exposures to children under the age of 6 years old. Children under the age of 6 years exhibit unique activities that do not occur at older ages. Therefore, a separate assessment for children under 6 years old has been conducted. In addition, dermal and inhalation route-specific assessments were also conducted.

The following information has been excerpted from Cohen (2008). NHANES are a series of US national surveys of the health and nutrition status of the non-institutionalized civilian population conducted by the Centers for Disease Control and Prevention. As part of the 2003-2004 NHANES, urinary concentrations (µg/L) of triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) were measured on a random sample of 2,517 participants of ages 6 and over. These measurements represent concentrations in spot urine samples. The corresponding human dose (mg/kg/day) was not measured or estimated by NHANES. The NHANES urinary metabolite concentration data collection efforts were not designed to directly determine the dose and CDC has not reported dose estimates for triclosan based on NHANES measurement data. The NHANES 2003-2004 data were obtained from the NHANES website: www.cdc.gov/nchs/nhanes.htm See the *Triclosan Occupational and Residential Exposure Assessment*, dated September 8, 2008 for more details on NHANES.

The NHANES results are believed to be representative of a range of acute to chronic exposures to children and adults because of the relatively short half-life of triclosan in urine

(i.e., 11 hours) and the often daily use of triclosan products such as hand soaps and tooth paste. The upper range of exposures is important because of the uncertainties in converting the spot urine concentrations to a dose; because the pharmacokinetic data appears to be highly variable for triclosan; and because the use of triclosan by the NHANES population is unknown. Interpreting the NHANES data for triclosan as representing a range of acute to chronic exposures is also supported by the fact that the 2,517 samples selected for analyses of triclosan were randomly selected from the total NHANES random population of 9,643, and therefore, *"…the representative design of the survey was maintained"* (Calafat et al 2007). Given the uncertainties in aggregating screening-level single use exposure estimates and assumptions on co-occurrence of uses, the NHANES data are viewed to be a reasonable data set to use for predicting aggregate risks.

The Agency used conservative assumptions assessing the spot urine concentrations to err on the side of overestimating the potential dose. Conservative assumptions used in the assessment include: 1) assumptions used by Cohen (2008) for the dose conversion (e.g., 95th percentile of urinary volume assumed for all individuals); 2) the characterization of the risks if one were to assume the pharmacokinetics of triclosan at the lowest (most conservative) urinary excretion (urinary excretion ranged from 24 to 83 percent with a median of 54 percent); and 3) the inclusion of these conservative assumptions even at the upper percentile of exposure. Future refinements to using the NHANES data for the triclosan risk assessment should focus on refining these parameters.

The residential post-application assessment is protective of long-term exposure. The results of the NHANES aggregate risks using the most conservative methodology option assessed for those 6+ years old indicate mean MOEs ranging from 4,700 to 19,000. At the 99th percentile the MOEs range from 260 to 1,700. For infants 6 to 12 months old, the mean NHANES 6-11 year old MOEs combined with bounding estimates for infant-specific activities for nursing, object-to-mouth, and hand-to-mouth exposures indicate an aggregate MOE of 390. At the 99th percentile NHANES distribution combined with the infant-specific activities indicate a MOE of 290. Including exposures to the FDA-regulated soaps and toothpaste for 6-11 year olds is a conservative assessment of exposure from these products to 6 to 12 month olds.

Based on the low vapor pressure of triclosan and the lack of aerosol generation over time by the application methods (excluding bystanders in the vicinity of airless spraying of paint which triggers risks of concern), inhalation exposure is expected to be minimal. This expectation is confirmed by the MOEs estimated to be in the millions for breathing triclosan-contaminated dust. The potential for dermal irritation to occur from direct contact with products treated at low concentrations of triclosan are expected to be minimal. See the *Revised Triclosan Occupational and Residential Exposure Assessment*, dated September 8, 2008, for more detailed information.

Dermal Irritation

The potential for dermal irritation to occur from incidental dermal exposures from products (impregnated textiles, fabrics such as clothing items and mattresses) treated at low concentrations of triclosan are expected to be minimal.

Dermal Systemic

There is the potential for dermal-specific route of exposure to adults and children contacting impregnated textiles and fabrics such as clothing items and mattresses. The contribution of dermal exposure to the aggregate exposure is represented in the NHANES data. Nonetheless, a post-application screening-level clothing assessment to represent exposure to treated textiles and fabrics is provided. The route-specific dermal toxicological endpoint for the intermediate-term exposure duration is used to represent all textile uses. Long-term duration was not assessed because transferable triclosan residues from treated textiles and fabrics are not expected to be available continuously at the levels used in this screening-level assessment.

The dermal MOEs for adults and toddlers are equal to or above the target MOE of 100. The calculations of the intermediate-term post-application dermal doses and MOEs for adults and toddlers wearing treated clothing are shown in Table 4.9 of the *Revised Triclosan Residential and Occupational Risk Assessment*, dated September 8, 2008.

Infant-Specific Exposure Pathways

While NHANES data are measured exposures that represent the real world co-occurrence of triclosan-treated products, it is necessary to use screening-level deterministic assessments as well as to make assumptions of potential co-occurrence of triclosan-treated products for younger children. An assessment of infants in the 6 to 12 month old age group has been selected to represent the high end of exposure activities of children less then six years old to triclosan-treated products. This age group is considered the high end of exposure based on the characteristics discussed in Table 2 presented in USEPA (2005) and the likelihood of these activities co-occurring. USEPA (2005) indicates that this age group includes behaviors that would lend themselves to potentially expose children to triclosan-treated products. Characteristics of children at this age that potentially exposes children to triclosan that would not have been captured by the 6-11 year old age category in NHANES include nursing, increasingly likely to mouth nonfood items, and *"development of personal dust clouds"* as a characteristic relevant to inhalation exposure.

Infant-specific activities resulting in potential exposures that are not accounted for by the 6-11 year old age group in NHANES that are likely to co-occur include:

- Nursing (i.e., triclosan-contaminated breast milk);
- Object-to-mouth exposures (e.g., mouthing of plastic items such as toys, combs & brushes, playground equipment);
- Hand-to-mouth exposure (e.g., residues in dust stuck to children's hands); and;
- Inhalation of triclosan-contaminated dust.

Other potential exposure pathways for infants in the 6 to 12 month old age group that are captured – and overestimated for the 6 to 12 month olds -- by the NHANES age groups 6-11 years old include:

- Brushing teeth with triclosan-treated tooth paste;
- Washing hands with triclosan-treated antibacterial soap;
- Exposure to impregnated fabrics and textiles such as clothing/sportswear, blankets, mattresses, tooth brush bristles, etc. that may be treated with triclosan; and
- Exposure to impregnated polymers and plastics such as food contact surfaces (e.g., cutting boards, conveyor belts, counter and table tops).

The MOEs for each of the infant-specific exposure pathways are listed below. See the *Revised Triclosan Occupational and Residential Exposure Assessment*, dated September 8, 2008 for the details of this assessment including MOE calculations.

Nursing

The daily dose for an infant 6 to 12 months old is estimated to be 0.005 mg/kg/day. The MOE is 6000 (i.e., chronic NOAEL of 30 mg/kg/day / daily dose 0.005 mg/kg/day) which is above the target MOE of 100 and therefore indicate no risks of concern.

Object-to-mouth

The MOE of 430 is above the target MOE of 100 and is not of concern.

Hand-to-mouth

The calculation of the short- and intermediate-term oral doses (toxicological endpoint selected is also protective of the long-term duration) and the oral MOEs are shown in Table 4.6 of the *Revised Triclosan Residential and Occupational Risk Assessment*, dated September 8, 2008. The oral MOEs are above the target MOE of 100 (short-term MOE = 1E+6 and the intermediate- and long-term MOE = 6.7E+6).

Dust Inhalation

The resulting route-specific inhalation MOEs are in the millions, with a target MOE = 1,000. Therefore, inhalation to triclosan-contaminated dust is considered to be negligible.

4. Aggregate Exposure and Risk

The Agency performed an assessment of the aggregate exposure to triclosan. Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources including triclosan FDA uses such as hand soaps and toothpaste, and from all known or plausible exposure routes (oral, dermal, and inhalation). An aggregate risk assessment was conducted using the single selected toxicological endpoint for acute dietary, short-term (1-30 days), intermediate-term (1-6 months), and chronic (several months to lifetime) exposure durations. Inhalation aggregate risks are minimal based on the low vapor pressure of triclosan

and uses such as tooth paste, hand soap, and impregnated textiles that do not involve inhalation as the primary route of exposure. Further discussion of inhalation exposure can be found in the *Revised Triclosan Occupational and Residential Exposure Assessment*, dated September 8, 2008.

In performing aggregate exposure and risk assessments, the Office of Pesticide Programs has published guidance outlining the necessary steps to perform such assessments (General Principles for Performing Aggregate Exposure and Risk Assessments, November 28, 2001; available at http://www.epa.gov/pesticides/trac/science/aggregate.pdf). Steps for deciding whether to perform aggregate exposure and risk assessments are listed, which include: identification of toxicological endpoints for each exposure route and duration; identification of potential exposures for each pathway (food, water, and/or residential); reconciliation of durations and pathways of exposure with durations and pathways of health effects; determination of which possible residential exposure scenarios are likely to occur together within a given time frame; determination of magnitude and duration of exposure for all exposure combinations; determination of the appropriate technique (deterministic or probabilistic) for exposure assessment; and determination of the appropriate risk metric to estimate aggregate risk.

In the case of triclosan, population-based biological monitoring data are available to assess the co-occurrence of uses to develop an aggregate exposure assessment. The population-based biological monitoring data are believed to be a more accurate predictor of aggregate exposure because not only are the data triclosan specific, they are also based on actual consumer use of the various triclosan products as they co-occur in practice. Although the aggregate exposure/risk assessment using the NHANES data provides an encompassing review of all triclosan-treated products, it does not include exposures to children under the age of 6 years old. Children under the age of 6 years exhibit unique activities that do not occur at older ages. Therefore, a separate assessment for children under 6 years old has been included. The potential dermal-specific route of exposure to adults and children contacting impregnated textiles and fabrics such as clothing items and mattresses is represented in the NHANES data.

a. Aggregate Risk for Children (6 years) to Adults

All exposure durations were assessed using the selected oral NOAEL of 30 mg/kg/day with a target MOE of 100. The oral endpoint was selected to represent the various oral exposure scenarios that are expected from antimicrobial exposure to triclosan. The calculated MOEs are representative of all exposure durations. The NHANES data show that 74.6% of the samples had detectable levels of total (free plus conjugated) triclosan. Tables 5.1 and 5.2 in the *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan) Risk Assessment for the Reregistration Eligibility Decision (RED) Document*, dated September 15, 2008 provide the mean and 99th percentiles, respectively, of the spot urine concentration to dose conversion prior to correcting for the 54% triclosan urinary excretion (in units of ug/kg/day); the pharmacokinetic 54% corrected daily dose converted to units of mg/kg/day; and the MOEs (for each of the three basic concentration to dose conversion methods). Aggregate exposures and risks are presented for the following age groups and

subpopulations: all age groups; ages 6-11; ages 12-19; ages 20-59; ages >=60; males; females, Mexican-American; White, non-Hispanic; and Black, non-Hispanic.

The results of the aggregate risks at both the mean and 99th percentile do not trigger risks of concern. The mean MOEs range from 4,700 to 19,000 (target MOE = 100). The MOEs at the 99th percentile of the dose range from 260 to 1,700 (target MOE = 100). The MOE is 120 when applying the lowest and most conservative percent urinary excretion from the results of the pharmacokinetic data (i.e., 24 percent) to the most conservative dose conversion method (i.e., Geigy's 95th percentile of daily urine volumes). In conclusion, even with the reliance of conservative assumptions in estimating risks to account for the considerable uncertainties in converting spot urine concentration to dose, the NHANES data as analyzed for triclosan sufficiently characterize the aggregate risks as meeting the definition of not resulting in unreasonable adverse effects.

b. Aggregate Risk for Infants

While NHANES data are measured exposures that represent the real world co-occurrence of triclosan-treated products, it is necessary to use screening-level deterministic assessments as well as to make assumptions of potential co-occurrence of triclosan-treated products for younger children. *USEPA (2005) Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants*, an internally and externally scientific peer reviewed document, provides the basis of the age group selection. The age group of 6 to 12 months old was selected to represent behavioral activities of children younger than 6 years old that are exposed to triclosan-treated products. Characteristics of children at this age that potentially exposes children to triclosan that would not have been captured by the 6-11 year old age category in NHANES include nursing, increasingly likely to mouth nonfood items (e.g., toys, combs & brushes, playground equipment), and *"development of personal dust clouds"* as a characteristic relevant to inhalation exposure. The aggregate risks for infants 6 to 12 months old have been estimated by combining the mean NHANES distribution with the infant-specific bounding risks, with the exception of the inhalation risks as they were considered negligible (MOEs in the millions and therefore these risks do not effect the aggregate results). See the *Revised Triclosan Residential and Occupational Risk Assessment,* dated September 8, 2008 for more information on the infant-specific exposure pathways. The aggregate MOE from the measured mean of the 6-11 year old NHANES subjects combined with the bounding risks from nursing, object-to-mouth, and hand-to-mouth indicate a long-term MOE of 390 (target MOE = 100). The 99th percentile of the NHANES dose (when using the 95% urine volume to estimate the 99th percentile dose) is combined with the infant-specific bounding risks and indicates a long-term MOE of 290 (target MOE = 100). See the *Triclosan Residential and Occupational Exposure Assessment*, dated September 8, 2008 for more information regarding the infant aggregate exposure assessment.

5. Occupational Exposure and Risk

Because triclosan is currently registered for use in occupational settings (including HVAC coil spray applications, as a materials preservative in paints and in industrial processes and water systems for pulp and paper), occupational handlers have the potential to be exposed to triclosan through mixing, loading or applying a pesticide or following application of products containing triclosan. Table 6 presents the representative occupational uses assessed for triclosan. Occupational non-cancer risks are presented as margins of exposure (MOE).

Table 6. Representative Exposure Scenarios Associated with Occupational Exposures to Triclosan

Representative Use	Method of Application	Exposure Scenario	Example Registration #	Application Rate
Commercial/Industrial/Institutional Premises (Use Category III)				
HVAC coil applications	Airless sprayer	ST/IT Handler: Inhalation	82523-1	6.1E-4 lb ai/10 ft^2 (0.85 pints/10 ft^2 x 1 gal/8 pts x 8.34 lb/gal x 0.69% ai)
Painting (commercial painters)	Paint brush, Airless sprayer	ST/IT Handler: Inhalation	42182-1	0.1 lb a.i./gallon [up to 1% product x 99% a.i. x 10 lb/gal paint density = 0.099 lb a.i./gallon of paint]
Material Preservatives (Use Category VII)				
Paint	Liquid pour, Powder	ST/IT Handler: inhalation	42182-1	0.1 lb a.i./gallon [up to 1% product x 99% a.i. x 10 lb/gal paint density = 0.099 lb a.i./gallon of paint]
Industrial processes and water systems (Use Category VIII)				
Pulp and Paper	Metered pump	ST/IT Handler: Inhalation	70404-5	2% a.i. by weight of paper product (2% product by weight x 99% a.i. for paper mulch) Note : other labels for paper and paper board have lower rates, 42182-1 and 3090-165)

To assess handler risk, the Agency used surrogate unit exposure data primarily from the proprietary Chemical Manufacturers Association (CMA) Antimicrobial Exposure Study (USEPA 1999) and the Pesticide Handlers Exposure Database (PHED) (USEPA 1998). For the occupational scenarios in which CMA data were insufficient, other data and methods were applied. For additional information, please see the *Revised Triclosan Residential and Occupational Exposure Assessment*, dated September 8, 2008.

Using conservative assumptions, most estimated risks from exposure to triclosan in occupational settings did not exceed the Agency's level of concern during application. However, Table 7 presents the application occupational risks for triclosan that exceeded EPA's level of concern. The calculated dermal MOEs were below the target MOE of 100 for the commercial painters (both applying by brush and airless sprayer) and the application during pulp & paper manufacture. The inhalation MOEs are below the target MOE of 1000 for the airless sprayer (paint), the paint manufacturing, and the pulp and paper. However, a request has been received by the Agency from the registrants to voluntarily cancel the paint use (inclusive of stains and coatings). Once the action to terminate the paint use is completed, any risks associated with triclosan-treated paint will be mitigated. See Section IV of this document for EPA's triclosan risk management strategy.

Table 7. Short- and Intermediate-Term Inhalation and Intermediate-Term Dermal Risks Associated with Occupational Handlers

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)		Application Rate	Quantity Handled/ Treated per day	Daily Dose (mg/kg/day)[a]		MOE[b] (Target MOEs = 1000 for inhalation; 100 for dermal)	
		Inhalation	Dermal			Inhalation	Dermal	Inhalation	Dermal
Commercial, Institutional and Industrial Premises and Equipment (Use Site Category III)									
HVAC	Airless sprayer	0.83	38	6.1E-4 lb ai/10ft^2	Large building 1000 ft^2	0.00072	0.033	4,500	1,200
Painting (commercial)	Paint brush	0.26	180	0.1 lb a.i./gal	5 gallons	0.002	1.3	1,600	**31**
	Airless sprayer	0.83	38		50 gallons	0.059	2.7	**54**	**1**
Material Preservatives (Use Site Category VII)									
Paint (manufacturing process)	Liquid pour	0.00346	0.135 (gloves)	0.99% a.i.	20,000 lbs	0.0098	0.38	**330**	110
	Liquid pump	0.000403	0.00629 (gloves)		200,000 lbs	0.011	0.18	**290**	220
Industrial Processes and Water Systems (Use Site Category VIII)									
Pulp and Paper	Metering pump	0.000403	0.00629 (gloves)	2% a.i.	500 tons	0.115	1.8	Require closed loading systems to mitigate the exposure/risk	

a Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) x absorption factor (1 for inhalation and 1 for dermal) x application rate x quantity treated / body weight (70 kg).

b MOE = LOAEL or NOAEL (mg/kg/day) / daily dose [Where inhalation LOAEL = 3.21 mg/kg/day for all inhalation exposure durations and the IT dermal NOAEL is 40 mg/kg/day from a dermal route-specific study]. Target MOE = 1000 for inhalation and 100 for dermal.

Occupational post-application dermal and inhalation exposures are assumed to be negligible based on the use patterns.

6. Incident Reports

There are no incident reports associated with exposure to end-use products containing triclosan.

B. Environmental Fate and Ecological Hazard Assessment

The Agency has conducted an environmental fate assessment and an ecological hazard assessment for triclosan to support the reregistration eligibility decision. It should be noted that an ecological risk assessment is not ordinarily conducted when the registered use patterns are considered to be "indoor use" because of the limited potential for these use patterns to result in environmental exposure. However, triclosan has been detected in natural waterways; therefore, the Agency believes it is prudent to conduct a qualitative risk assessment using surface water monitoring data.

The following risk characterization is intended to describe the magnitude of the estimated ecological hazards and environmental risks associated with the use of EPA-registered triclosan products. The Agency evaluated the submitted environmental fate and ecological studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision. In addition, a Tier 1, *Down-the-Drain (DTD) module* and a *Probabilistic Dilution Model (PDM)* was performed to simulate industrial process wastewater releases, resulting from the uses of triclosan as a material preservative. The *Down-the-Drain (DTD) module* estimates concentrations of triclosan found in surface water to which aquatic organisms may be exposed as a result of potential releases of triclosan from consumer uses and the *Probabilistic Dilution Model (PDM)* estimates the number of days per year that the concentration of triclosan in surface water exceeds the concentration of concern for aquatic organisms. For detailed discussions of all aspects of the environmental risk assessment, see the *Revised Environmental Fate Assessment of Triclosan for the Issuance of the Reregistration Eligibility Decision Document*, dated September 11, 2008, and the *Revised Ecological Hazard and Environmental Risk Assessment of Triclosan for the Reregistration Eligibility Decision (RED) Document,* dated September 11, 2008.

1. Environmental Fate

a. Hydrolysis

Triclosan [5-chloro-2-(2,4-dichlorophenoxy)phenol] is a white crystalline powder with low solubility in water (12 ppm). Triclosan is hydrolytically stable under abiotic and buffered conditions over the pH 4-9 range based on data from a preliminary test at 50°C. Photolytically, triclosan degrades rapidly under continuous irradiation from artificial light at 25°C in a pH 7 aqueous solution, with a calculated aqueous photolytic half-life of 41 minutes. One major degradation product has been identified, DCP (2,4-dichlorophenol), which was a maximum of 93.8-96.6% of the applied triclosan at 240 minutes post-treatment.

In soil, triclosan is expected to be immobile based on an estimated K_{oc} of 9,200. Triclosan is not expected to volatilize from soil (moist or dry) or water surfaces based on an estimated Henry's Law constant of 1.5×10^{-7} atm-m^3/mole. Triclosan exists partially in the dissociated form in the environment based on a pKa of 7.9, and anions do not generally adsorb more strongly to organic carbon and clay than their neutral counterparts. In aquatic environments, triclosan is expected to adsorb to suspended solids and sediments and may

bioaccumulate (K_{ow} 4.76), posing a concern for aquatic organisms. There is a low to moderate potential for bioconcentration in aquatic organisms based on a BCF range of 2.7 to 90.

b. Biodegradability

Hydrolysis is not expected to be an important environmental fate process due to the stability of triclosan in the presence of strong acids and bases. However, triclosan is susceptible to degradation via aqueous photolysis, with a half-life of <1 hour under abiotic conditions, and up to 10 days in lake water. An atmospheric half-life of 8 hours has also been estimated based on the reaction of triclosan with photochemically produced hydroxyl radicals. Additionally, triclosan may be susceptible to biodegradation based on the presence of methyl-triclosan following wastewater treatment.

2. Ecological Hazard

As mentioned previously, the Agency used surface water monitoring data to evaluate the ecological risks associated with the antimicrobial uses of triclosan. In addition, the Agency used toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics and pesticide use data. The toxicity endpoints used in the ecological hazard assessment were obtained from guideline toxicity studies conducted for wildlife, aquatic organisms, and plants (40 CFR §158.2060). A summary of the submitted data is provided below.

a. Environmental Toxicity

Toxicity to Birds

One available acute oral study on the bobwhite quail indicates that triclosan is only slightly toxic to birds (LD_{50} of 825 mg/kg). A subacute dietary study using the TGAI may be required on a case-by-case basis depending on the results of lower-tier ecological studies and pertinent environmental fate characteristics in order to establish the toxicity of a chemical to avian species. The preferred-test species is either the mallard duck or bobwhite quail. The results of these two acceptable studies indicate that triclosan is relatively nontoxic to avian species through subacute dietary exposure (LC_{50} of >5000 ppm).

Toxicity to Terrestrial Animals

Refer to the *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Risk Assessment for the Reregistration Eligibility Decision (RED) Document* dated September 15, 2008 for details on the available acute mammalian toxicity studies submitted for human health assessment and for information on triclosan's potential as an endocrine disruptor.

Toxicity to Aquatic Animals

One acute toxicity study is required to establish the toxicity of triclosan to freshwater fish. The preferred test species is either the rainbow trout (*Oncorhynchus mykiss*), a coldwater fish, or the bluegill (*Lepomis macrochirus*), a sunfish. For triclosan, acute studies are available for the rainbow trout and the bluegill and for the fathead minnow (*Pimephales promelas*). The acute toxicity values from these studies categorize triclosan as being highly

toxic to freshwater fish (96-hr LC_{50} of 0.26 – 0.288 mg/L). A precautionary label statement is required.

One study is required to establish the acute toxicity (EC_{50}) of triclosan to freshwater invertebrates. The preferred test species is *Daphnia magna*, a water flea. Two studies categorize triclosan as being highly toxic to freshwater invertebrates (48-hr LC_{50} of 0.39-0.42 mg/L) and therefore a precautionary label statement is required. However, neither study satisfied the guideline requirement (OPPTS 850.1010) for current uses.

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or the active ingredient is toxic to aquatic organisms and is expected to reach this environment via other transport pathways. At this time this testing is not required for triclosan, but is dependent upon the results of environmental modeling and monitoring which are required to support reregistration of triclosan (see *Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document, dated September 11, 2008*).

Chronic toxicity testing (fish early life stage and aquatic invertebrate life cycle) is required for pesticides when certain conditions of use and environmental fate apply. The preferred freshwater fish test species is the fathead minnow. At this time this testing is not required for triclosan, but is dependent upon the results of environmental modeling and monitoring which are required to support reregistration of triclosan (see *Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document, dated September 11, 2008*).

Toxicity to Plants

Non-target plant phytotoxicity testing is required for pesticides when certain conditions of use and environmental fate apply. At this time this testing is not required for triclosan, but is dependent upon the results of environmental modeling and monitoring which are required to support reregistration of triclosan (see *Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document, dated September 11, 2008*).

Testing has been conducted with triclosan on several aquatic plant species. Testing is normally conducted with one species of aquatic vascular plant (*Lemna gibba*) and four species of algae: (1) freshwater green alga, *Selenastrum capricornutum,* (2) marine diatom, *Skeletonema costatum,* (3) freshwater diatom, *Navicula pelliculosa,* and (4) bluegreen cyanobacteria, *Anabaena flos-aquae.* The rooted aquatic macrophyte rice (*Oryza sativa*) is also tested in seedling emergence and vegetative vigor tests.

Four studies that evaluate the toxicity of triclosan to freshwater aquatic plants have been submitted. Results of these studies are presented in Table 6 of the *Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document, dated September 11, 2008*. Note that in a search of the available data on triclosan, the U.S. EPA's Office of Water found an EC_{50} as

low as 0.0007 mg/L for the green alga *Scenedesmus subspicatus* and an EC_{25} as low as 0.00067 mg/L for the blue-green alga *Anabaena flos-aquae* (U.S. EPA, 2007).

The guideline requirement for an algal toxicity test (850.5400, 123-2) is partially fulfilled. One additional algal toxicity test under 850.5400 is outstanding: a test with the freshwater green alga, *Selenastrum capricornutum*. The other non-target aquatic plant toxicity requirement, floating freshwater aquatic macrophyte duckweed (*Lemna gibba*), guideline 850.4400, is satisfied. Studies on the rooted freshwater macrophyte rice (*Oryza sativa*), 850.4225 and 850.4250 (2 tests on seedling emergence and vegetative vigor) have not been submitted.

Toxicity to Honeybees

Honeybee toxicity data are not needed based on the current uses of triclosan.

b. Ecological Exposure and Risk

An ecological risk assessment is not typically conducted for the types of triclosan uses registered with the EPA because of the limited potential for ecological exposure. However, since triclosan has been detected in natural waters, a qualitative environmental risk assessment was performed using monitoring levels of triclosan found in waterways and toxicity values from the tables in section I of the *Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document,* dated September 11, 2008 to develop risk quotients (RQs) and compare them to levels of concern (LOCs) for triclosan. LOCs were not exceeded for fish but were exceeded for aquatic plants. The RQs were based on published literature, submitted data and USGS monitoring data. A meta-analysis of literature, plus exposure modeling was used to conduct a probabilistic assessment of triclosan. This analysis sheds light on the difficulties associated with relating laboratory data to field effects and concludes that additional studies may be needed to refine scientific knowledge of metabolites and degradates, bioaccumulation factors, endocrine-related effects, and community level impacts. There were no acceptable acute toxicity studies for freshwater invertebrates or estuarine and marine organisms nor were there any acceptable chronic toxicity studies available for aquatic organisms. Therefore, risk to these species could not be assessed at this time. The hazard assessment will be used to meet current labeling needs and to determine hazard endpoints for ecological organisms potentially exposed in the event of a spill or other potential environmental releases.

In addition, the Agency performed *consumer environmental modeling* for triclosan. See the Appendix to the *Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document,* dated September 11, 2008 titled *Estimates of Exposures and Risks To Aquatic Organisms from Releases of Triclosan to Surface Water as a Result of Uses Under EPA's Jurisdiction*, and the *Revised Environmental Fate Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document*, dated September 11, 2008. The consumer environmental modeling (DTD module and PDM) assumed that all triclosan used in the manufacture of the antimicrobial uses is released into surface waters. After adjustments,

these models concluded that estimated concentrations of triclosan in surface water do not exceed concentrations of concern for acute risk presumptions for any of the aquatic organisms and plants (vascular and non-vascular). As discussed in the *Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document,* dated September 11, 2008, only acute concentrations of concern were evaluated for aquatic organisms since acceptable chronic aquatic data are not available. However, considering the low probability of triclosan being released into household wastewater and surface waters from the antimicrobial uses, the Agency also concludes that chronic aquatic risks are unlikely from consumer uses of triclosan-treated plastic and textile items. Therefore, Agency can reasonably conclude that the antimicrobial uses of triclosan (e.g., triclosan-treated plastic and textile items in households) are unlikely to contribute significant quantities of triclosan into household wastewater and eventually to surface water.

As discussed in the *Revised Environmental Fate Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document*, dated September 11, 2008, little is known about how much, if any, triclosan is released from industrial sites (where triclosan is incorporated into plastic and textile items) into effluents and the environment (e.g., surface waters). Considering this, the Agency is requiring that the technical registrants perform environmental modeling and monitoring to address this issue. Until the Agency receives these data it is unable to calculate risk quotients specific to these industrial scenarios. However, the Agency does not anticipate risks of concern. The confirm this, the modeling and monitoring data will be required. In the event a new risk of concern is identified, the Agency will revisit the issue. The registrants are required to sample effluents from such facilities and receiving (surface) waters adjacent to these facilities, determining the extent and duration of triclosan and major degradates/metabolites (e.g., triclosan methyl). Depending on the results of this monitoring, further ecological effects data may be required. In addition, four studies to address bioaccumulation potential will also be called-in. See Chapter V. of this RED document and the *Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document*, dated September 11, 2008, for more information on the potential ecological effects data to be called in.

3. Risk to Listed Species

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

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. This preliminary analysis indicates that there is a potential for triclosan use to overlap with listed species and that a more refined assessment is warranted, to include direct, indirect and habitat effects.[1] The more refined assessment should involve clear delineation of the action area associated with proposed use of triclosan and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this assessment and therefore an endangered species effect determination will not be made at this time. The refined endangered species assessment will be performed under the Registration Review program (see http://www.epa.gov/oppsrrd1/registration_review/ for more information) and will include a species by species analysis.

1 The Agency is making this statement because triclosan and triclosan transformation products are being detected in various environmental components (see *Revised Environmental Fate Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document*, dated September 11, 2008).

IV. Reregistration and Risk Management Decisions

A. Determination of Reregistration Eligibility

1. Reregistration Eligibility Decision

Section 4(g)(2)(A) of FIFRA calls for EPA to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. EPA has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing triclosan as an active ingredient. The Agency has reviewed these generic data, and has determined that the data are sufficient to support a reregistration eligibility decision for all products containing triclosan.

The Agency completed its assessment of the residential, occupational, indirect dietary and ecological risks associated with the use of pesticide products containing the active ingredient triclosan. The Agency has determined that most triclosan containing products are eligible for reregistration provided that: 1) all risk mitigation measures are implemented; 2) current data gaps and confirmatory data requirements are addressed; and 3) label amendments are made as described in Section V. Use as a materials preservative in paint (inclusive of stains and coatings) has been requested to be voluntarily cancelled by the registrants and is not eligible for reregistration. Appendix A summarizes the uses of triclosan that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of triclosan and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

The Agency considered the available information and has determined that the uses of triclosan that appear in Appendix A of this document will not pose unreasonable risks to humans or the environment if the conditions and requirements for reregistration outlined in this document are implemented. Unless labeled and used as specified in this document, triclosan would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the conditions and requirements for reregistration identified in this document, the Agency may take regulatory action to address the potential risk concerns from the use of triclosan.

a. Endocrine Disruption Effects

Under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, the Agency is required to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen

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

There is some evidence that triclosan disrupts thyroid hormone homeostasis and interacts with the androgen and estrogen receptors. The available evidence is summarized in the *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document,* dated August 29, 2008. The Agency is aware that research is ongoing regarding endocrine effects of triclosan, and this further research may require future modification to the risk assessment and the RED for triclosan. The EPA process of regulating pesticides allows for reevaluation at any time if new information becomes available.

b. Cumulative Risks

Risks summarized in this document are those that result only from the use of triclosan. The Food Quality Protection Act (FQPA) 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." 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 triclosan. The Agency acknowledges that triclocarban has been detected along with triclosan in the environment. Although there may be some structural similarity between triclosan and triclocarban, these chemicals belong to two different classes (hydroxyphenylether and hydroxyphenylurea respectively). Further, there is not necessarily a relationship between the mechanism of antimicrobial activity and mechanism of toxicity in mammals. As defined in the Office of Pesticide Programs' 2002 document "Guidance on Cumulative Risk Assessment of Pesticide Chemicals that Have a Common Mechanism of Toxicity," available at: http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf, common mechanism of toxicity refers to "two or more pesticide chemicals or other substances that cause a common toxic effect by the same, or essentially the same, sequence of major biochemical events…" There is currently insufficient evidence characterizing major biochemical events between triclosan and triclocarban to suggest that these two chemicals share a common mechanism of toxicity.

c. Public Comments and Response

Through EPA's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for triclosan. During the public comment period on the risk assessments, which closed on July 7, 2008, the Agency received multiple comments from the technical registrants, members of the public, and various environmental groups.

All comments are available at http://www.regulations.gov under docket number EPA-HQ-OPP-2007-0513. The Agency's official responses will also be posted in the public docket.

2. Regulatory Rationale

With the exception of the paint use which has been requested to be voluntarily cancelled by the registrants, the Agency has determined that triclosan is eligible for reregistration provided that the risk mitigation and data requirements outlined in this document are fully implemented. A summary of EPA's rationale for reregistering and managing risks associated with triclosan is presented below. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V. of this document.

a. Performing Residential Activities

There are no EPA registered products containing triclosan that can be applied directly by the homeowner. However, there is a homeowner application of triclosan when it is used as an in-can preservative for latex paint. To estimate the potential risks associated with this exposure, the Agency assessed handler exposures for the in-can preservative use in paint. The calculated inhalation MOEs are above the target MOE of 1000 for the paint brush scenario but below the target MOE for the airless sprayer scenario (i.e., MOE = 180). Because the estimated risks associated with treated paints exceeded EPA's level of concern by such a large degree – in some cases by more than several orders of magnitude – the Agency believes that this use does not meet the "no unreasonable adverse effects" criteria of FIFRA. Personal protective equipment (PPE) such as respirators is not a viable mitigation option for residential paint uses for an in-can preservative. The paint use (inclusive of stains and coatings) has been requested to be voluntarily cancelled by the registrants and is not eligible for reregistration. Once the action to terminate the paint use is completed, any risks associated with triclosan-treated paint will be mitigated.

Based on the aggregate risk assessment, the Agency believes that certain other residential uses of triclosan (see Appendix A) result in significantly lower exposure and risk. Therefore, residential uses other than paints, stains, and coatings meet the "no unreasonable adverse effects" criteria of FIFRA and are eligible for reregistration.

b. Performing Occupational Activities

There is the potential for workers to be exposed to triclosan during the application of triclosan products in an occupational setting (handler exposure). However, occupational post-application exposures are assumed to be negligible based on the use patterns. To estimate the potential risks associated with occupational handler exposure, the Agency assessed representative application scenarios including treated paints and the industrial processes and water systems use for pulp and paper.

Short-term dermal irritation exposures and risks were not estimated for occupational handler exposures. Instead, dermal irritation exposures and risks will be mitigated using default PPE requirements based on the toxicity of the end-use products. For occupational

uses dermal irritation risks are mitigated by requiring the user to wear PPE (e.g., chemical resistant gloves and clothing). Mitigating with PPE is only a viable option for pesticide-labeled products (i.e., a label is needed to inform workers to wear PPE). Therefore, the Agency often requires workers using pesticide-labeled products (concentrated form) in the manufacturing setting (where workers are applying the active ingredient to the paint itself) to wear PPE to mitigate dermal irritation. Conversely, for in-can material preservatives there is no pesticide label that goes with the preserved product to inform the workers/painters that PPE is needed (there is no pesticide label on a can of paint). Thus PPE is only a viable option in an occupational setting where triclosan is being applied to the paint, but not a viable option when occupational handlers are actually applying the paint itself.

For the intermediate-term dermal risks, the MOEs were above the target MOE of 100, and therefore, not of concern except for the commercial painter and material preservative uses for pulp and paper. The intermediate-term MOEs for using a paint brush/roller and an airless sprayer are 31 and 1, respectively (target MOE = 100). Again, because triclosan is used as a material preservative in the paint, the use of chemical resistant gloves on the label is impractical. However, the paint use (inclusive of stains and coatings) has been requested to be voluntarily cancelled by the registrants. Once the action to terminate the paint use is completed, any risks associated with triclosan-treated paint will be mitigated. For the pulp and paper use, dermal risks will be mitigated by requiring the use of a closed delivery system.

For the occupational handler inhalation exposure and risk assessment, the MOEs were below the target MOE for all scenarios except for the brush application for paints. The inhalation MOE for commercial use of an airless sprayer for paints is 54 (target MOE = 1000), for liquid pour and liquid pump during paint manufacturing 330 and 290 (target MOE = 1000), respectively. The paint use (inclusive of stains and coatings) has been requested to be voluntarily cancelled by the registrants. Once the action to terminate the paint use is completed, any risks associated with triclosan-treated paint will be mitigated. For the pulp and paper use, inhalation risks can be mitigated by requiring the use of a closed delivery system.

However, the Agency believes that certain other occupational uses of triclosan (see Appendix A) result in significantly lower exposure and risk. Therefore, occupational uses other than paints, stains, and coatings meet the “no unreasonable adverse effects” criteria of FIFRA and are eligible for reregistration provided the mitigation measures and associated label changes presented in Table 8 and Table 10 are implemented.

c. Ecological Risk Management

A qualitative environmental risk assessment was performed using monitoring levels of triclosan found in waterways and toxicity values from the tables in section I of the *Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document,* dated September 11, 2008 to develop risk quotients (RQs) and compare them to levels of concern (LOCs) for triclosan. LOCs were not exceeded for fish but were exceeded for aquatic plants. In addition, the Agency performed *consumer environmental modeling* for triclosan. The consumer environmental modeling assumed that all triclosan used in the manufacture of the antimicrobial uses is released into surface waters. After adjustments, these models concluded that estimated concentrations of triclosan in surface water do not exceed concentrations of concern for acute risk presumptions for any of the aquatic organisms and plants (vascular and non-vascular). Considering the low probability of triclosan being released into household wastewater and surface waters from the antimicrobial uses, the Agency also concludes that chronic aquatic risks are unlikely from consumer uses of triclosan-treated plastic and textile items. Therefore, Agency can reasonably conclude that the antimicrobial uses of triclosan (e.g., triclosan-treated plastic and textile items in households) are unlikely to contribute significant quantities of triclosan into household wastewater and eventually to surface water.

Environmental modeling and monitoring specific to plastic and textile *facilities,* where triclosan is incorporated into these items, is required. The technical registrants will be required via the DCI to sample effluents from such facilities and receiving (surface) waters adjacent to these facilities, determining the extent and duration of triclosan and major degradates/metabolites (e.g., triclosan methyl). Prior to beginning the environmental monitoring the registrants must submit a protocol to the Agency for approval. Depending upon the results of this modeling and monitoring effort, the following ecological effects data may be required (these studies are held in reserve):

1) Freshwater invertebrate acute study (850.1010) [Technical Grade Active Ingredient (TGAI)];
2) Estuarine/marine fish acute study (850.1075) (TGAI)];
3) Estuarine/marine shrimp acute study (850.1035) (TGAI);
4) Estuarine/marine mollusk acute study (850.1025) (TGAI);
5) Fish early life-stage (freshwater) study (850.1400) (TGAI);
6) Aquatic invertebrate (freshwater) life-cycle study (850.1300) (TGAI);
7) Fish life-cycle study (850.1500) (TGAI);
8) Acute sediment toxicity to freshwater invertebrates (850.1735) (TGAI);
9) Acute sediment toxicity to estuarine invertebrates (850.1740) (TGAI); and
10) Additional plant toxicity testing: an additional algal toxicity test (850.5400) with the freshwater green alga, *Selenastrum capricornutum*; and studies on the rooted freshwater macrophyte, rice (*Oryza sativa*) – 850.4225 and 850.4250 (2 tests on seedling emergence and vegetative vigor)
11) Oyster bioconcentration study – BCF (850.1710) (major degradate/metabolite of triclosan – e.g., methyl triclosan)
12) Fish bioconcentration study – BCF (850.1730) (major degradate/metabolite of

triclosan – e.g., methyl triclosan)
13) Chironomid sediment toxicity test (850.1790) (major degradate/metabolite of triclosan – e.g., methyl triclosan)
14) Aquatic food chain transfer (850.1850) (major degradate/metabolite of triclosan – e.g., methyl triclosan)
15) Chronic sediment toxicity to freshwater and/or estuarine invertebrates (no guideline number) (TGAI)

In addition, four studies to address bioaccumulation potential will also be required via the DCI (850.1850; 850.1710; 850.1730; and 850.1790). Prior to conducting these studies, the registrants must submit protocols to the Agency for approval.

B. Risk Management Decision

Triclosan uses presented in Appendix A are eligible for reregistration provided that registrants comply with the requirements outlined in this document including implementing risk mitigation measures, amending product labels, and submitting required confirmatory data. In addition, the Agency is aware of recent research conducted by the Office of Research and Development on the effects of triclosan on thyroid homeostasis in the rat (US EPA, 2008). These data were considered in selection of the incidental oral endpoint, but the current endpoint was retained, as further investigation is needed on the effects of triclosan on the thyroid. The Agency will continue to monitor the toxicity profile of triclosan and will amend the assessment as needed. Further, given the rapidly developing scientific database for triclosan, the Agency intends to accelerate the schedule for the registration review process for this chemical. Currently, the Agency intends to begin that process in 2013, ten years earlier than originally planned.

1. Risk Mitigation Measures

Products containing triclosan are eligible for reregistration provided that the registrants implement the risk mitigation measures presented in Table 8. Specific label language to implement these measures is presented in Table 10. In the future, registrants may request that the Agency remove or reduce certain restrictions or mitigation measures upon submission of acceptable toxicity and exposure studies that demonstrate to the Agency that risk exposure to triclosan is below the Agency's level of concern.

Table 8. Risk Mitigation Measures for Triclosan

Use Site	Risk(s) of Concern	Mitigation Measures
Paints, Stains, and Coatings	Residential handler inhalation exposure to triclosan in paint when applying paint	• A request has been received by the Agency from the registrants to voluntarily

	Occupational handler dermal and inhalation exposure to triclosan when applied to paint in manufacturing setting	
	Occupational handler inhalation exposure to triclosan when applying paint	
Pulp and Paper	Occupational handler inhalation and dermal exposure to triclosan when applied during pulp and paper manufacturing (used in the industrial water processing systems)	• Closed systems must be used

2. Product Label Amendments

Manufacturing-Use Products and End-Use Products are to be amended to reflect the mitigation measures presented in Table 8 and the label amendments presented in Table 10 (see Section V).

3. Antimicrobial Resistance

Antimicrobial resistance differs from antibiotic resistance, the latter of which can be a concern in hospital or medical settings. There is currently some research attempting to demonstrate a connection between antimicrobial resistance and antibiotic resistance in regard to triclosan, but the linkage has not been expressly proven. The Agency continues to look into the issue of antimicrobial resistance and its links to antibiotic resistance through review of current literature and membership in the *Interagency Task Force on Antimicrobial Resistance.* The Task Force has a number of goals stated in the *Public Health Action Plan to Combat Antimicrobial Resistance* (http://www.cdc.gov/drugresistance/actionplan/aractionplan.pdf). Though none of the goals are associated with a specific active ingredient, many of the activities are expected to further our understanding of the processes involved with antimicrobial resistance, which may subsequently further our understanding of any potential resistance from the use of triclosan. Some of the goals are as follows:

- Evaluate the benefits and risks incorporating antimicrobial, disinfectant, or antiseptic chemicals into consumer products (e.g., soap, toys, kitchen utensils, clothes, paints, plastics, and film preservatives) and of applying disinfectants and sanitizers to hard, non-porous surfaces such as food-contact surfaces, hospital premises, bathrooms, etc. Consider whether they have any efficacy in reducing infection and/or may play a role in promoting drug resistance;

- Convene an expert group to consider how to incorporate antimicrobial resistance (AR) issues into regulations governing the registration and use of antimicrobials and antibiotic pesticides. Invite external experts, stakeholders, and the public to provide input;

- Determine which organisms and susceptibility to specific antimicrobial drugs should be under surveillance and create a mechanism for periodic updating of this list;

- Develop and implement procedures for monitoring antimicrobial use in human medicine, agriculture, veterinary medicine, and consumer products;

- Conduct pilot studies to assess the extent of environmental contamination by antimicrobial drug residues and drug-resistant organisms that enter the soil or water from human and animal wastes. If contamination is detected, conduct appropriate surveillance in waste, surface and ground water, and soil from agricultural areas in which waste is used for fertilizer, and conduct studies to determine potential impact on human and animal health;

- Gather information on the relationship between antimicrobial pesticide and herbicide use and the emergence of drug-resistance by monitoring;

- Establish an ongoing mechanism to obtain periodic input from external experts on AR issues. This process will include ensuring from stakeholders and partners in developing and reviewing federal efforts to address antimicrobial resistance

4. Post-RED Activities

The Agency recognizes that there is a considerable amount of ongoing research regarding triclosan. The Agency will track the progress of these studies and, as new scientific data becomes available, will review this data. The Agency will then determine what, if any, changes to the risk assessment and risk management decision are necessary. The Agency will also continue to participate actively in the *Interagency Task Force on Antimicrobial Resistance* described above and evaluate information that results from that activity. Further, given the rapidly developing scientific database for triclosan, the Agency intends to accelerate the schedule for the registration review process for this chemical. Currently, the Agency intends to begin that process in 2013, ten years earlier than originally planned

V. What Registrants Need to Do

The Agency has determined that triclosan is eligible for reregistration provided that the conditions and requirements for reregistration identified in this RED are implemented (see Section IV). The registrants will also need to amend product labeling for each product.

The database supporting the reregistration of triclosan has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, additional confirmatory data are required to support continued registration.

A. Manufacturing Use Products

1. Generic Data Requirements

The generic database supporting the reregistration of triclosan for currently registered uses has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, the confirmatory data presented in Table 9 are required. CMA, PHED, environmental fate and surface water monitoring studies are all required. The ecological studies are being held in reserve pending the outcome of the surface water monitoring studies. Specific deadlines are set forth in the generic data call-in (GDCI), including those for submission of initial responses and/or request for time extensions or data waivers as well as for other required steps. Deadlines for submitting generic data are also set forth in the GDCI.

Table 9. Generic Data Required to Support Triclosan Registrations

EPA Guideline Number	Requirement Name
Ecological Studies	
Special Study for Surface Water Modeling	Environmental modeling and monitoring specific to plastic and textile facilities where triclosan is incorporated into these items
850.1710	Oyster Bioconcentration Test
850.1730	Fish Bioconcentration Test
850.1850	Aquatic Food Chain Transfer
850.1790	Chironomid sediment toxicity test
Environmental Fate Study	
835.4400	Anaerobic Aquatic Metabolism
Confirmatory CMA and PHED Studies	
875.1700	Product Use Information (applicator)
875.2700	Product Use Information (post-applicator)
875.2800	Description of Human Activity
875.1200[1]	Dermal Indoor Exposure
875.1400[2]	Inhalation Indoor Exposure
875.2300	Indoor Surface Residue Dissipation (infant assessment for mouthing toys)
875.1600	Applicator Exposure Monitoring Data Reporting

Table 9. Generic Data Required to Support Triclosan Registrations	
EPA Guideline Number	**Requirement Name**
875.2900	Data Reporting and Calculations
Studies to be Held in Reserve Pending Outcome of Surface Water Monitoring Data	
850.1010	Aquatic invertebrate acute toxicity, test, freshwater daphnids
850.1075	Fish acute toxicity test, marine
850.1035	Mysid acute toxicity test
850.1025	Oyster acute toxicity test (shell deposition)
850.1300	Daphnid chronic toxicity test
850.1400	Fish early-life stage toxicity test
850.1500	Fish life cycle toxicity
850.1735	Whole sediment acute toxicity invertebrates, freshwater
850.1740	Whole sediment acute toxicity invertebrates, marine
850.4225	Seedling emergence, Tier II
850.4250	Vegetative vigor, Tier II
850.5400	Acute Algal Dose-Response Toxicity – Green Algae (Selenastrum Capricornutum)
850.1710	Oyster bioconcentration study – BCF (major degradate/metabolite of triclosan – e.g., methyl triclosan)
850.1730	Fish bioconcentration study – BCF (major degradate/metabolite of triclosan – e.g., methyl triclosan)
850.1790	Chironomid sediment toxicity test (major degradate/metabolite of triclosan – e.g., methyl triclosan
850.1850	Aquatic food chain transfer (major degradate/metabolite of triclosan – e.g., methyl triclosan)
No current guideline number	Chronic sediment toxicity to freshwater and/or estuarine invertebrates (no guideline number) (TGAI)

[1 & 2] These studies are required for all manufacturing settings where "liquid pour" is the application method of triclosan

Environmental modeling and monitoring specific to plastic and textile facilities, where triclosan is incorporated into these items, is required. The technical registrants are required to sample effluents from such facilities and receiving (surface) waters adjacent to these facilities, determining the extent and duration of triclosan and major degradates/metabolites (e.g., triclosan methyl). Prior to beginning the environmental monitoring the registrants must submit a protocol to the Agency for approval. Depending upon the results of this modeling and monitoring effort, the above aforementioned ecological effects data may be required (these studies are held in reserve).

Four studies to address bioaccumulation potential will also be called-in (850.1850;

850.1710; 850.1730; and 850.1790). Prior to conducting these studies, the registrants must submit protocols to the Agency for approval.

Surrogate dermal and inhalation unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study or from the Pesticide Handler Exposure Database (PHED). Since the CMA data are of poor quality, the Agency requires that confirmatory data be submitted to support the occupational scenarios assessed in this document. The quantities handled/treated were estimated based on information from various sources, including HED's Standard Operating Procedures (SOPs) for Residential Exposure Assessments (USEPA, 2000 and 2001), and personal communication with experts. The individuals contacted have experience in these operations and their estimates are believed to be the best available without undertaking a statistical survey of the uses. In certain cases, no standard values were available for some scenarios. Assumptions for these scenarios were based on AD estimates and could be further refined from input from registrants.

For triclosan technical grade active ingredient products, the registrant is required to submit the following items:

Within 90 days from receipt of the generic data call-in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. Submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Heather Garvie at (703) 308-0034 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
Heather Garvie
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Heather Garvie
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

B. End-Use Products

1. 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.

The PDCI will set forth specific deadlines including those pertaining to submission of response forms or requests for time extensions and/or waivers as well as for other required steps. Deadlines for submitting product-specific data will also be provided.

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

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

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

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

Within eight months from the receipt of the PDCI:

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

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

3. Five copies of the draft label incorporating all label amendments outlined in Table 17 of this document;

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

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

6. The product-specific data responding to the PDCI.

Please contact Emily Mitchell at (703) 308-8583 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk
Emily Mitchell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Emily Mitchell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is presented in Table 10. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

Table 10. Required Label Changes for Manufacturing and End-Use Products Containing Triclosan

Description	Triclosan: Required Labeling Language	Placement on Label
Manufacturing-Use Products		
For all Manufacturing Use Products	"Only for formulation as a preservative 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
For all Manufacturing Use Products that have toys as a use site	"When used for formulation as a materials preservative for toys, the active ingredient amount must be limited to no more than 0.5%."	Directions for Use
For all Products that state paint as a use site on the label	The paint use site must be removed from the label.	Directions for Use
For all Manufacturing Use Products	"When used in industrial process waters for the manufacture of pulp and paper, a closed delivery systems must be used."	Directions for Use

VI. APPENDICES

Triclosan Appendix A: Use Patterns Eligible for Reregistration

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Commercial, institutional and industrial premises and equipment				
Air Conditioning Heat Exchange Coils	82523-1	Spray (Fine Mist)	0.85 US pts./ 10 sq ft. (400 ml/ m^2) based on a 4" (100 mm) deep coil at 12 FPI.	For application by a service contractor
Residential and public access premises				
Air Conditioning Heat Exchange Coils	82523-1	Spray (Fine Mist)	0.85 US pts./ 10 sq ft. (400 ml/ m^2) based on a 4" (100 mm) deep coil at 12 FPI.	For application by a service contractor
Materials preservatives				
Personal Care Products: bristles & Handles of brushes (tooth, hair) combs, incontinence care products, razors	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
	83884-9	incorporated in the fiber/textile or applied directly to it	.1% - 1% a.i. based on weight of finished product	Not for use in diapers
Textiles & Fibers Sanitizer (natural and Synthetic in contact with Human Skin)	3090-165	Incorporated into production of end use product	0.7 to 1.0% of product based on weight of finished product	Do not use in the manufacture or treatment of items that may come in contact with food. Do not use for production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
				products or products intended to decrease the transmission of disease. Finished products incorporating the product may not make claims of antimicrobial activity that exceed what is permitted in PR Notice 2000-1
Home Furnishings: blankets, cloths, countertops, curtains, draperies, linens, napkins	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
	83884-9	incorporated in the fiber/textile or applied directly to it	.1% - 1% a.i. based on weight of finished product	Not for use in diapers
Textiles	6390-25	Padding or Exhaustion	Apply to leave 0.25% - 1.0% of product on the dry weight of the fiber.	For manufacturing use only.
	10466-42	Application directly to the textile	Apply 1%-1.5% of the product based on weight of material being treated	None Listed
	10466-24	Exhaustion, padding or co-treatment with resins and softeners	Add at 1 to 3.5% on weight of material being treated	Do not use for any applications involving direct or indirect food contact or human or animal drinking water contact applications.
	3090-215	Incorporation	0.1% to .5% of product	Do not use in the manufacture or treatment of

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		into fiber	based on the weight of material being treated	items that may come in contact with food. Do not use for production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care products or products intended to decrease the transmission of disease. Finished products incorporating the product may not make claims of antimicrobial activity that exceed what is permitted in PR Notice 2000-1
	10466-27	Padding or Exhaustion	1 to 5% based on fabric weight and durability requirements. Inclusive of air filters, cleaning cloths, non-woven wipes	Not to be used on food contact surfaces
	10466-42	Incorporation into textiles	1%-1.5% based on weight of finished product	
	10466-38	Incorporated into PVC used in coated or laminated textiles	0.05% - 0.3% based on weight of finished product	
	83884-7	Incorporation into textiles	Up to 5% of the product based on weight of the finished product	
	42182-1	Incorporated into	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		production of end use product		antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
	3090-165	Pad, jig or dyeback	0.7 to 1.0% of Product; can also be used for paper and leather	Do not use in the manufacture or treatment of items that may come in contact with food. Do not use for production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care products or products intended to decrease the transmission of disease. Finished products incorporating the product may not make claims of antimicrobial activity that exceed what is permitted in PR Notice 2000-1
	70404-5	Incorporation into product or applied as finish	.1%-2% based on weight of finished product	Not for use in diapers
	83884-10	Incorporation into product or applied as finish	.1%-2% based on weight of finished product	Not for use in diapers
	83884-9	incorporated in the fiber/textile or applied directly to it	.1% - 1% a.i. based on weight of finished product	Not for use in diapers
Carpets & Rugs	42182-1	Incorporated into	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		production of end use product		antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
	10466-27	Padding; exhaustion	1-4% based on weight of finished product	
	83884-9	incorporated in the fiber/textile or applied directly to it	.1% - 1% a.i. based on weight of finished product	Not for use in diapers
Shoe & Boot Spray	10466-42	Spray	1%-1.5% based on weight of finished product	
PVC (foils, films, coatings, artificial leather, plastisols, extruded and injection moulded articles, PVC tiles and fibers)	3090-219	Incorporated into production of end use product	Apply such that the finished product contains 0.5% to 1.4% by weight of the additive	Do not use in the manufacture or treatment of items that may come in contact with food. Do not use for production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care products or products intended to decrease the transmission of disease. Finished products incorporating the product may not make claims of antimicrobial activity that exceed what is permitted in PR Notice 2000-1
Plastics	2829-139	Incorporated into production of end use product	Up to 2.5% a.i.	When used for formulation as a materials preservative for toys, the active ingredient amount must be limited to no more than 0.5%.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	2829-145	Incorporated into production of end use product	Up to 2.5% a.i.	When used for formulation as a materials preservative for toys, the active ingredient amount must be limited to no more than 0.5%.
	3090-215	Incorporation into plastic	0.1% to .5% of product based on the weight of material being treated	Do not use in the manufacture or treatment of items that may come in contact with food. Do not use for production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care products or products intended to decrease the transmission of disease. Finished products incorporating the product may not make claims of antimicrobial activity that exceed what is permitted in PR Notice 2000-1
	4822-429	Incorporated into production of end use product	0.06% a.i.	Impregnated plastic bag; not for use for food storage
	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product (some examples include toys, cutting boards, toothbrush bristles & handles, storage containers, brooms)	Active concentration is limited to 0.5% for toys and ice-making equipment; Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	70404-5	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	
	83884-10	Incorporation into product or applied as finish	.1%-2% based on weight of finished product	
	10466-38	Incorporation into finished product	5-10% of product based on weight of finished product	
	83884-9	incorporated in the plastic or applied directly to it	.15% - 1% a.i. based on weight of finished product	
Synthetic cellulosic sponges	10466-27	Incorporated into manufacturing process	1-4% based on weight of finished product	
Polymer Compounds	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
	70404-5	Incorporated into	.1% - 1% a.i. based on weight of finished product	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		manufacturing process		
	83884-10	Incorporation into product or applied as finish	.1%-2% based on weight of finished product	
	3090-215	Incorporation into polymer	0.1% to .5% of product based on the weight of material being treated	Do not use in the manufacture or treatment of items that may come in contact with food. Do not use for production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care products or products intended to decrease the transmission of disease. Finished products incorporating the product may not make claims of antimicrobial activity that exceed what is permitted in PR Notice 2000-1
	83884-9	incorporated in the polymer or applied directly to it	.15% - 1% a.i. based on weight of finished product	
Pulp & Paper	42182-1	Incorporation into finished product	.1% - 1% a.i. based on weight of finished product	When used in industrial process waters for the manufacture of pulp and paper, a closed delivery systems must be used; Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
	3090-165	Pad, jig or	1% of product	When used in industrial process waters for the

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		dyeback		manufacture of pulp and paper, a closed delivery systems must be used. Do not use in the manufacture or treatment of items that may come in contact with food. Do not use for production of baby diapers or fibers for the production of baby diapers. Do not use for the production of health care products or products intended to decrease the transmission of disease. Finished products incorporating the product may not make claims of antimicrobial activity that exceed what is permitted in PR Notice 2000-1
Floor coverings (carpets, rugs, mats, sealer/wax components	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product (for example: adhesives, caulking, tiles, whirlpools)	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
Inks, Dispersions, Pigment Presscakes	10466-27	Formulation into end use products intended to treat the article itself.	1-4% based on weight of product	Not for use in food-grade inks
Construction & building materials	42182-1	Incorporated into production of end use	.1% - 1% a.i. based on weight of finished product (for example: adhesives, caulking, tiles, whirlpools)	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		product		of bacteria, mold, mildew and fungi in or on the treated product.
Polyethylene Sleeves for Buried Conduits	10466-38	Incorporated into production of end use product	Up to 2% based on weight of finished product	
Adhesvies	10466-27	Incorporated into production of end use product	1-4% based on weight of product	Not for use on food grade adhesives
	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product; Not for use on food grade adhesives
Polymeric systems	10466-42	Incorporation into production of end-use product	4%-1.5% based on weight of goods	
	10466-38	Incorporation into production of end-use product	0.05% - 3% based on weight of goods; inclusive of synthetic fibers, molded plastics and synthetic foams	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Vinyl Film: Garment Bags, Blanket Bags, Cubicle Curtains	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
Polyethylene, Polypropylene, Vinyl, Nylon, Latex and products of similar matrix	5383-127	Incorporated into production of end use product	0.5%-1.0% by weight of the fabric	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
Polypropylene, Nylon and Acrylic Fibers and blends of these fibers with cotton	5383-127	Incorporated into production of end use product	Incorporated at a percent ranging from 0.1% to 1.5% by weight of the fabric	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
Industrial Materials: air filters, air filtration media, janitorial supplies, trays, wipes, respirator mask components, conveyor belts	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
Ice Making Equipment	42182-1	Incorporated into	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		production of end use product		antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
Sporting Goods: boating/marine equipment, exercise & gym equipment, playground equipment	42182-1	Incorporated into production of end use product	.1% - 1% a.i. based on weight of finished product	Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product.
Technical Registration	70404-2 73951-1	For processing or manufacturing use only	N/A	

Appendix B: Triclosan (Case 2340)

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

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

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

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

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

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

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	3,4,7	42027901 45358501
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	3,4,7	42027901 45358502 45487201
830.1670	61-2b	Formation of Impurities	3,4,7	42027901 42027902 43277802 45358503 45358504
830.1700	62-1	Preliminary Analysis	3,4,7	42027902 45358504
830.1750	62-2	Certification of Limits	3,4,7	42027901 43277802 43533901 45358503 45358505
830.1800	62-3	Analytical Method	3,4,7	42027902 45358506
830.6302	63-2	Color	3,4,7	42027902 45358502
830.6303	63-3	Physical State	3,4,7	42027902
830.6304	63-4	Odor	3,4,7	42027902
830.7200	63-5	Melting Point	3,4,7	42027904
830.7220	63-6	Boiling Point	3,4,7	N/A
830.7300	63-7	Density	3,4,7	42027904

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7840 830.7860	63-8	Solubility	3,4,7	42027904 47261401 47261403 47261404 47261406 47261407
830.7950	63-9	Vapor Pressure	3,4,7	42027904 47261403 47261404 47261406 47261407
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	3,4,7	42027902 42027904
830.7000	63-12	pH	3,4,7	N/A
830.6313	63-13	Stability	3,4,7	42027902 43022601 43277801
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test, Bobwhite Quail	3,4,7	41008910
		Avian Acute Oral Toxicity Test, Bobwhite Quail		43022602
		Avian Acute Oral Toxicity Test, Mallard Duck		43022603
850.2200	71-2	Avian Dietary Toxicity Test, Bobwhite Quail	3,4,7	41008911 43022604
850.1075	72-1	Fish Acute Toxicity – Freshwater, Rainbow Trout	3,4,7	41008912 43969301
		Fish Acute Toxicity – Freshwater, Bluegill Sunfish		41008913

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1075	72-1	Estuarine/Marine – Fish Acute Toxicity	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1010	72-2	Aquatic Invertebrate Acute Toxicity, Daphnia	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1025	72-3	Oyster acute toxicity test (shell deposition)	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1035	72-3	Mysid acute toxicity test	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1300	72-4	Daphnia Chronic Toxicity Test	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1400	72-4	Fish early-life stage toxicity test	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1500	72-5	Fish life cycle toxicity	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1710	72-6	Oyster bioconcentration study	3,4,7	Data Gap
850.1710	72-6	Oyster bioconcentration study – BCF (major degradate/metabolite of triclosan – e.g., methyl triclosan)	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1730	72-6	Fish bioconcentration study	3,4,7	Data Gap

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1730	72-6	Fish bioconcentration study – BCF (major degradate/metabolite of triclosan – e.g., methyl triclosan)	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1790	72-6	Chironomid sediment toxicity test	3,4,7	Data Gap
850.1790	72-6	Chironomid sediment toxicity test (major degradate/metabolite of triclosan – e.g., methyl triclosan)	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1850	none	Aquatic food chain transfer	3,4,7	Data Gap
850.1850	none	Aquatic food chain transfer (major degradate/metabolite of triclosan – e.g., methyl triclosan)	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.1735	none	Whole sediment acute toxicity invertebrates, freshwater	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1740	none	Whole sediment acute toxicity invertebrates, marine	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.4225	123-1	Seedling Emergence, Tier II	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
850.4250	123-1	Vegetative Vigor, Tier II	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*))
850.5400	123-2	Acute algal dose-response toxicity – marine diatom	3,4,7	44422801
		Acute algal dose-response toxicity – freshwater diatom	3,4,7	
		Acute algal dose-response toxicity – bluegreen cyanobacteria	3,4,7	
		Acute algal dose-response toxicity - duckweed	3,4,7	

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.5400	123-2	Algal toxicity, Tiers 1 and II	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
No current guideline number		Chronic sediment toxicity to freshwater and/or estuarine invertebrates (TGAI)	3,4,7	Study being held in reserve pending outcome of surface water monitoring (Special Study, *Environmental Modeling and Monitoring Specific to Plastic and Textile Facilities where Triclosan is Incorporated into these Items*)
Special Study for Surface Water Monitoring		Environmental modeling and monitoring specific to plastic and textile facilities where triclosan is incorporated into these items		Data Gap
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	3,4,7	43206901
870.1200	81-2	Acute Dermal - Rabbit	3,4,7	94044 100178
870.1300	81-3	Acute Inhalation - Rat	3,4,7	43206902 43310501
870.2400	81-4	Primary Eye Irritation - Rabbit	3,4,7	94045
870.2500	81-5	Primary Dermal Irritation - Rabbit	3,4,7	42306903
870.2600	81-6	Dermal Sensitization	3,4,7	43206502
870.3100	82-1a	90- Day Oral Sub-chronic - Rodent	3,4,7	133545 43022605 43389707

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.3150	82-1	90- Day Oral Sub-chronic Non-rodent	3,4,7	96102
870.3250	82-3	90-Day Dermal Toxicity - Rat	3,4,7	43328001
870.3465	82-4	28/90-Day Inhalation - Rat	3,4,7	0087996
		Developmental Toxicity -Rat	3,4,7	43817502 43817503
		Developmental Toxicity – Mouse	3,4,7	43817501
870.3700	83-3	Developmental Toxicity – Non-rodent	3,4,7	43022607 43820401 43787101
870.3800	83-4	2 Gen. Reproduction and Fertility Effects	3,4,7	40623701
870.4100a	83-1a	Chronic Toxicity – Hamster	3,4,7	44751101
870.4100b	83-1b	Chronic Toxicity – Baboon	3,4,7	133230
870.4200	83-2	Carcinogenicity – Mouse	3,4,7	FDA Review
870.4300	83-5	Chronic/Oncogenicity – Rat	3,4,7	161332, 42047906
870.5100	84-2	Bacterial Reverse Mutation Test	3,4,7	44389705
870.5300	84-2	In vitro Mammalian Cell Gene Mutation Test	3,4,7	44389704
870.5375	84-2	In vitro Mammalian Chromosome Aberration Test	3,4,7	47276601
870.5385	84-2	Micronucleus Assay	3,4,7	43740802
870.5500	84-2	Bacterial DNA Damage or Repair Test	3,4,7	47276602
870.7485	85-1	Metabolism and Pharmacokenetics	3,4,7	45307501, 45307502, 45307503
870.7600	85-3	Dermal Penetration	3,4,7	34335
ENVIRONMENTAL FATE				
835.2110	161-1	Hydrolysis	3,4,7	42027908

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
835-2240	161-2	Photodegradation in Water	3,4,7	43022608
835.4100	162-1	Aerobic Soil Metabolism	3,4,7	47261401
835.4400	162-3	Anaerobic Aquatic Metabolism	3,4,7	Data gap
835.4300	162-4	Aerobic Aquatic Metabolism	3,4,7	47261402
OCCUPATIONAL AND RESIDENTIAL EXPOSURE				
875.1700		Product Use Information (applicator)	3,4,7	Data gap
875.2700		Product Use Information (post-applicator)	3,4,7	Data gap
875.2800	133-1	Description of Human Activity	3,4,7	Data gap
875.1200	233	Dermal Indoor Exposure	3,4,7	Data gap
875.1400	234	Inhalation Indoor Exposure	3,4,7	Data gap
875.2300		Indoor Surface Residue Dissipation (infant assessment for mouthing toys)	3,4,7	Data gap
875.1600	236	Applicator Exposure Monitoring Data Reporting	3,4,7	Data gap
875.2900	134	Data Reporting and Calculations	3,4,7	Data gap

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The triclosan docket (EPA-HQ-OPP-2007-0513) initially contained the April 17, 2008 preliminary risk assessment and the related supporting science documents. EPA then considered comments on the risk assessment and revised the risk assessment and supporting chapters as necessary. The revised risk assessment, supporting science chapters and Response to Comments document will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

http://www.regulations.gov

These documents include:

- Triclosan Preliminary Risk Assessment; Notice of Availability and Risk Reduction Options, 05/07/2008.

Preliminary Risk Assessment and Supporting Science Documents:

- 5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Risk Assessment for the Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, Antimicrobials Division, April 17, 2008.
- Preliminary Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, February 22, 2008, Genevieve Angle, Biologist.
- Environmental Fate Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, February 06, 2008, Srinivas Gowda, Microbiologist/Chemist.
- Product Chemistry Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, October 17, 2007, Srinivas Gowda, Microbiologist/Chemist.
- Dietary Risk Assessment for Triclosan for the RED Process. Case No 2340. PC Code: 054901, April 5, 2007, A. Najm Shamim, PhD., Chemist
- Triclosan, Occupational and Residential Exposure Assessment. Case No 2340. PC Code: 054901, Antimicrobials Division, April 17, 2008.
- Revised 5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document. Case No

2340. PC Code: 054901, May 14, 2008, Tim McMahon, Ph.D., Senior Toxicologist

- Triclosan: Report of the Cancer Assessment Review Committee, Jessica Kidwell, January 4, 2008

Revised Risk Assessment and Supporting Science Documents (RED Supporting Documents):

- Reregistration Eligibility Decision (RED) Document for Triclosan. Case No 2340. PC Code: 054901, Antimicrobials Division, September 18, 2008.
- 5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan**):** Risk Assessment for the Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, September 15, 2008, Tim McMahon, Ph.D., Senior Toxicologist.
- 5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Toxicology Chapter for the Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, August 29, 2008, Tim McMahon, Ph.D., Senior Toxicologist.
- Triclosan, Occupational and Residential Exposure Assessment. Case No 2340. PC Code: 054901, Antimicrobials Division, September 8, 2008.
- Revised Environmental Fate Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, September 11, 2008, Srinivas Gowda, Microbiologist/Chemist.
- Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, September 11, 2008, Richard C. Petrie, Agronomist, Team 3 Leader.
- TRICLOSAN: Revised Report of the Hazard Identification Assessment Review Committee and Antimicrobial Division Toxicity Endpoint Committee. August 29, 2008, Tim McMahon, Ph.D., Senior Toxicologist.
- Product Chemistry Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document. Case No 2340. PC Code: 054901, October 17, 2007, Srinivas Gowda, Microbiologist/Chemist.
- Dietary Risk Assessment for Triclosan for the RED Process. Case No 2340. PC Code: 054901, August 11, 2008, A. Najm Shamim, PhD., Chemist
- Estimates of Exposures and Risks to Aquatic Organism from Releases of Triclosan to Surface Water as a Result of Uses under the EPA's Jurisdiction. Risk Assessment and Science Support Branch (RASSB), Patricia Jennings, September 4, 2008

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the triclosan Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

1. MRID Studies

MRID #	Citation
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43429	Stenger, E.G.; Scharer, (1963) "Local Effects on Rabbit's Eye." (Unpublished study; prepared by J.R. Geigy, AG, Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:108210-J).
94044	Ullmann, L. (1980) Report on Acute Dermal LD50 in the Rabbit of FAT 80023/A: Project No. 800761. (Unpublished study received Jan 28, 1982 under 100-502; prepared by Ciba-Geigy Ltd., Switzer- land, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 246688-A)
94045	Ullmann, L. (1980) Report on Eye Irritation in the Rabbit after Single Application of FAT 80023/A: Project No. 801012. (Unpublished study received Jan 28, 1982 under 100-502; prepared by Ciba-Geigy Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246688-B)
96102	Burther, B.R.; Gordon, D.E. (1973) "Report to Ciba-Geigy Corporation: 90-day Subacute Oral Toxicity Study with Irgasan DP-300 in Beagle Dogs: IBT No. C1435." (Unpublished study; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:008400-C)
100178	Schoenig, G. (1967) "Report to Geigy Chemical Company: Acute Dermal Toxicity Study on CH 3565: IBT No. A5460." (Unpublished study; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:000503-D).
130187	Schoenig, G. (1967) "Report to Geigy Chemical Company: Acute Dermal Toxicity Study on CH 3565: IBT No. A5460." (Unpublished study; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:000503-D)
133545	Goldsmith, L. (1983) 90-Day Oral Toxicity Study in Rats with Fat 80'023/H: LBI Project No. 22188. Final Report. (Unpublished study received Dec. 23, 1983 under 100-502; submitted by Ciba-Geigy Corp.)

149464 Stierlin, H. (1972) Study of Pharmacokinetics and Metabolism in Mouse, Rat, Rabbit and Dog: GP 41 353: Report No. 33/1972. Un- published study prepared by Ciba-Geigy Ltd. 31 p.

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41008913 Terrell, Y. 1988. The Acute Toxicity Bioassay of Issue Plus on Bluegill Sunfish; Project No. 88-473; Prepared by American Standard Biosciences Corp. for Diversey Wyandotte Corporation, Wyandotte, Michigan.

41008914 Terrell, Y. 1988. Acute Toxicity of Issue Plus on *Daphnia magna*; Project No. 88-475; Prepared by American Standard Biosciences Corp. for Diversey Wyandotte Corporation, Wyandotte, Michigan.

42027901 LoMenzo, J. (1991) Irgasan DP 300: Product Identity and Composition. Unpublished study prepared by Ciba-Geigy Corp.

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42027904 Vogel, A. (1990) Irgasan 300 DP: Report on Melting Point/Melting Range. Unpublished study prepared by Ciba-Geigy Ltd.

42027906 Study 1 - Yau, E.T. and Green, J.D. (1986) Fat 80'023 2 Year Oral Administration to Rats; Study 2 – Parkes, D.G. (1986) Determination of Fat 80'023 in Blood and Tissue Samples Taken During a Two-Year Chronic Oral Toxicity/Oncogenicity Study in Albino Rats (24-month Final Report). Ciba-Geigy Corporation.

42027908 Pointurier, R. 1990. Irgasan® DP 300 – Report on Hydrolysis as a Function of pH. Unpublished study performed and submitted by Ciba-Geigy Ltd., Basel, Switzerland.

42306902 Duchosal F. and Ph. Thevenaz (1990) "4-Hour Acute Inhalation Toxicity Study with FAT 80'023/Q in Rats" Ciba-Geigy Ltd.

42306903 Sachsse, K.; Ullman, L. (1975) Skin Irritation in the Rabbits after Single Application of FAT 80'023/A. Unpublished Study Conducted by Ciba Geigy Ltd., Basel Switzerland. Project No. Siss 4719. Submitted to EPA by Chemical Division of Ciba Geigy Corp. (9/11/75).

42322101 Boettcher, J. 1990. Report on the Acute Toxicity (96h) of FAT 80, 023/Q to Zebrafish. Test No. G 069 04. Prepared by Ciba-Geigy, Ltd., D&C Product Ecotoxicology, Basel, Switzerland. Submitted by Ciba-Giegy Corporation, Greensboro, North Carolina.

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43022607 Schroeder, R.E. et al. (1992) "A Segment II Teratology Study in Rabbits with Irgacare MP" Bio/dynamics Inc.

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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the triclosan RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

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

Appendix G. Batching of Triclosan Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching at a later date.

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

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

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

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/.

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

Instructions

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

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

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

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

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.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 (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program—Storage and Disposal Statements

    b. 84-1 Clarification of Label Improvement Program

    c. 86-5 Standard Format for Data Submitted under FIFRA

    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

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

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

b. EPA Form No. 8570-4, Confidential Statement of Formula

c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

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

a. Registration Division Personnel Contact List

b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

c. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' Web Site

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

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

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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 Web site.

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

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
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 CAS number if one has been assigned.