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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 11, 2008

MEMORANDUM

SUBJECT: Revised Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan Reregistration Eligibility Decision (RED) Document

DP Barcode: 343548 **Reregistration Case No.:** 2340

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Chemical Name	PC Code	CAS#	Common Names
5-Chloro-2-(2,4-dichlorophenoxy)phenol	54901	3380-34-5	Triclosan

Attached is the Ecological Hazard and Environmental Risk Assessment Science Chapter for the Triclosan RED Document.

ECOLOGICAL HAZARD AND ENVIRONMENTAL
REVISED RISK ASSESSMENT CHAPTER
Triclosan

PC Code: 054901

CASE No.: 2340

09/11/08

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For Triclosan

Executive Summary:

Only a small portion of the uses of triclosan are regulated by the U.S. EPA and therefore covered in this document. Triclosan is currently registered by the EPA as a bacteriostat, fungicide/fungistat and mold/mildewcide for materials preservation, residential and public access premises and commercial, institutional and industrial premises and equipment. Its materials preservation uses include: adhesives, fabrics, vinyl, latex, plastics, polyethylene, polyurethane, synthetic polymers, styrene, floor wax emulsions, rope, textiles, caulking compounds, sealants, coatings, polypropylene, rubber, inks, cellulosic materials, slurries, films and latex paints. The residential and public access premises uses include: brooms, mulch, floors, shower curtains, awnings, tents, mattresses, toothbrushes, toilet bowls, urinals, garbage cans, refuse container liners, insulation, concrete mixtures, grouts, air filter materials, upholstery fabrics, and rugs/carpets. The commercial, institutional and industrial premises and equipment uses include: conveyor belts, fire hoses, dye bath vats and ice making equipment.

Assessment Based on Published Literature Including USGS Monitoring: An ecological risk assessment is not typically conducted for the types of uses registered for triclosan. However, since triclosan has been detected in natural waters, EPA performed a qualitative environmental risk assessment using monitoring levels of triclosan found in waterways and toxicity values from the tables in section I 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. 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.

Assessment Based On Consumer Environmental Modeling: Additionally, EPA performed consumer environmental modeling for triclosan [see attached Appendix (**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 chapter for triclosan]. The outcome of this consumer environmental modeling is that EPA concludes that for aquatic animals and plants (vascular and non-vascular), estimated concentrations of triclosan in surface water do not exceed concentrations of concern for acute risk presumptions for any of these organisms.[1] **What this means is that the Agency can reasonably conclude that the antimicrobial uses of triclosan (e.g., triclosan-treated plastic and textile items in**

1 As discussed in the revised triclosan environmental fate chapter, 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, EPA also concludes that chronic aquatic risks are unlikely from consumer uses of triclosan-treated plastic and textile items.

households) are unlikely to contribute significant quantities of triclosan into household wastewater and eventually to surface water.

Assessment For Industrial Use Scenarios: As discussed in the revised environmental fate chapter, 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 registrants perform environmental modeling and monitoring to address this issue. Until EPA receives these data we are unable to calculate risk quotients specific to these industrial scenarios.

Data Gaps:

Environmental modeling and monitoring specific to plastic and textile facilities, where triclosan is incorporated into these items, is required. The registrant is 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 registrant must submit a protocol to the Agency for approval.

The available published literature indicates the potential for triclosan to bioconcentrate and bioaccumulate in the environment. In order to better characterize this, the Agency is requiring the following four studies:

1) Oyster bioconcentration study – BCF (850.1710) [Technical Grade Active Ingredient (TGAI)] or Pure Active Ingredient, Radio-Labeled (PAIRA);
2) Fish bioconcentration study – BCF (850.1730) (TGAI or PAIRA);
3) Chironomid sediment toxicity test (850.1790) (TGAI or PAIRA); and
4) Aquatic food chain transfer test (850.1850) (TGAI or PAIRA).

Prior to beginning these four studies the registrant must submit protocols to the Agency for approval.

Additionally, depending upon the results of the modeling and monitoring effort and the above four studies, the following ecological effects data may be required:

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) Oyster bioconcentration study – BCF (850.1710) (major degradate/metabolite of triclosan – e.g., methyl triclosan);

9) Fish bioconcentration study – BCF (850.1730) (major degradate/metabolite of triclosan – e.g., methyl triclosan);
10) Chironomid sediment toxicity test (850.1790) (major degradate/metabolite of triclosan – e.g., methyl triclosan);
11) Aquatic food chain transfer (850.1850) (major degradate/metabolite of triclosan – e.g., methyl triclosan);
12) Acute sediment toxicity to freshwater invertebrates (850.1735) (TGAI);
13) Acute sediment toxicity to estuarine invertebrates (850.1740) (TGAI);
14) Chronic sediment toxicity to freshwater and/or estuarine invertebrates (no guideline number) (TGAI); and
15) Additional plant toxicity testing: an additional algal toxicity test (850.5400) with the freshwater green alga, *Selenastrum capricornutum* (TGAI); and studies on the rooted freshwater macrophyte, rice (*Oryza sativa*) – 850.4225 and 850.4250 (2 tests on seedling emergence and vegetative vigor) [Typical End-use Product (TEP)].

Label Hazard Statements/Use Recommendations:

Triclosan labels must state:

"This pesticide is toxic to fish and aquatic invertebrates."

"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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authorities are 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."

I. Ecological Toxicity Data

The toxicity endpoints presented below are based on the results of ecotoxicity studies submitted to EPA to meet the Agency's data requirements for the uses of triclosan.

A. Toxicity to Terrestrial Animals

(1) Birds, Acute

In order to establish the toxicity of triclosan to avian species, the Agency requires an acute oral toxicity study using the technical grade active ingredient (TGAI). The preferred-test species is either mallard duck (a waterfowl) or bobwhite quail (an upland game bird). The results of three acute oral toxicity studies, submitted for triclosan, are provided in the following table (Table 1).

Table 1. Acute Oral Toxicity of Triclosan to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/kg)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Mallard duck (*Anas platyrhynchos*)	Triclosan 99.7%	LD_{50} = >2150 NOAEL = 2150	Relatively nontoxic	Yes (core) - 14-day test duration - 19 weeks of age	430226-03
Bobwhite quail (*Colinus virginianus*)	Triclosan 99.7%	LD_{50} = 825 NOAEL = <147	Slightly toxic	Yes (core) - 14-day test duration - 21 weeks of age	430226-02
Bobwhite quail (*Colinus virginianus*)	Triclosan 3.89%	LD_{50} = >2000 NOAEL = N.R.	Relatively nontoxic	Yes (core for formulated product)	410089-10

These three acceptable acute oral toxicity studies indicate that triclosan is slightly toxic to relatively nontoxic to birds on an acute oral basis. The guideline requirement OPPTS 850.2100/(71-1) is satisfied.

(2) Birds, Subacute

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. This testing was required for triclosan. The preferred-test species is either the mallard duck or bobwhite quail. The results of two subacute dietary toxicity studies, submitted for triclosan, are provided in the following table (Table 2).

Table 2. Subacute Oral Toxicity of Triclosan to Birds

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (ppm)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Bobwhite quail (*Colinus virginianus)*	Triclosan 99.7%	LC_{50} (diet) = >5000 NOAEC = 1250	Relatively nontoxic	Yes (core) - 8-day test duration - 13 days of age	430226-04
Bobwhite quail (*Colinus virginianus)*	Triclosan 3.89%	LC_{50} (diet) = >5000 NOAEC = N.R.	Relatively nontoxic	Yes (core for formulated product) - 8-day test duration - 7-10 days of age	410089-11

The results of these two acceptable studies indicate that triclosan is relatively nontoxic to avian species through subacute dietary exposure. These studies fulfill guideline requirement OPPTS 850.2100/ (71-2a – Bobwhite quail/71-2b – Mallard duck).

(3) Mammals, Acute and Chronic Toxicity

Wild mammal testing is not required by the Agency. In most cases, rat toxicity values obtained from studies conducted to support data requirements for human health risk assessments substitute for wild mammal testing. Refer to the human toxicology chapter of this RED for mammalian toxicity data. Also, refer to the toxicology chapter for information on triclosan's potential as an endocrine disruptor.

B. Toxicity to Aquatic Animals

The Agency requested that aquatic toxicity studies be conducted with triclosan since, under typical use conditions, it may be introduced into the aquatic environment.

(1) Freshwater Fish, Acute

In order to establish the acute toxicity of triclosan to freshwater fish, the Agency requires freshwater fish toxicity studies using the TGAI. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). The results of 5 freshwater fish acute studies submitted for triclosan are presented in Table 3.

Table 3. Acute Toxicity of Triclosan to Freshwater Fish

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Rainbow Trout (*Oncorhynchus mykiss)*	Triclosan 99.3%	LC_{50} = 0.288 NOAEC = 0.100	Highly toxic	Yes (core) - 96-hr test duration - static test system	439693-01
Fathead minnow (*Pimephales promelas*)	Triclosan 99.7%	LC_{50} = 0.26 LOEC = 0.18 NOAEC = 0.10	Highly toxic	No (supplemental) - 96-hr test duration - static test system - nominal concentrations not verified	430460-01
Bluegill sunfish (*Lepomis macrochirus)*	Triclosan 3.89%	LC50 = 37.2 NOAEC = N.R.	Slightly toxic	Yes (core for formulated product) - 96-hr test duration - static test system	410089-13
Rainbow Trout (*Oncorhynchus mykiss)*	Triclosan 3.89%	LC_{50} = 23.4 NOAEC = N.R.	Slightly toxic	Yes (core for formulated product) - 96-hr test duration - static test system	410089-12

Freshwater acute toxicity tests indicate that triclosan is highly toxic to slightly toxic to fish on an acute basis. These studies fulfill guideline requirement OPPTS 850.1075 (72-1a&b). Because acute toxicity to fish is <1.0 mg/L, the environmental hazard section of triclosan labels must state: "This pesticide is toxic to fish."

(2) Freshwater Invertebrates, Acute

The Agency requires a freshwater aquatic invertebrate study using the TGAI to establish the acute toxicity to freshwater invertebrates. The preferred test species is *Daphnia magna*. The results of two studies submitted for triclosan are provided in the following table (Table 4). 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 0.13 mg/L for the Cladoceran *Ceriodaphnia dubia* (U.S. EPA, 2007).

Table 4. Acute Toxicity of Triclosan to Freshwater Invertebrates

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Toxicity Category	Satisfies Guidelines/ Comments	Reference (MRID No.)
Waterflea (*Daphnia magna)*	Triclosan 99.7%	EC_{50} = 0.39 NOAEC = 0.10 (a.i.)	Highly toxic	No (supplemental) - 48-hr test duration - static test system - nominal concentrations not verified	430460-02
Waterflea (*Daphnia magna)*	Triclosan 3.89%	LC_{50} = 0.42 NOAEC = N.R.	Highly toxic	No (supplemental) - 48-hr test duration - static test system - lack of pH and DO measurements and formulated product used	410089-14

The results of these studies indicate that triclosan is highly toxic to freshwater invertebrates. These studies **do not** fulfill guideline requirement OPPTS 850.1010 (72.2a). However, this data requirement is dependent upon the results of environmental modeling and monitoring which are required to support reregistation of triclosan. Because the acute aquatic invertebrate toxicity values are < 1.0 mg/L, the environmental hazard section of triclosan labels must state: "This pesticide is toxic to aquatic invertebrates."

(3) Estuarine and Marine Organisms, Acute

Acute toxicity testing with estuarine and marine organisms using the TGAI is required when the end-use product is intended for direct application to the marine/estuarine environment or effluent containing the active ingredient is expected to reach this environment. The preferred fish test species is the sheepshead minnow. The preferred invertebrate test species are mysid shrimp and eastern oysters. At this time this testing is not required for triclosan, but is dependent upon the results of environmental fate data which may be required. (See triclosan environmental fate chapter and comments above on potential data requirements). No studies have been submitted to fulfill these data requirements (OPPTS 850.1075/(72-3a), OPPTS 850.1035/(72-3c) and OPPTS 850.1025/(72-3b)).

(4) Aquatic Organisms, Chronic

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. The preferred freshwater invertebrate is *Daphnia magna*. 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 reregistation of triclosan. (See revised triclosan environmental fate chapter and comments above on potential data requirements). The results of one toxicity study submitted for triclosan is presented in Table 5. Note that in a search of the available data on triclosan, the U.S. EPA's Office of Water found a NOEC as low as 0.006 mg/L for the Cladoceran *Ceriodaphnia dubia* (U.S. EPA, 2007).

Table 5. Chronic Toxicity of Triclosan to Freshwater Organisms

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Waterflea (*Daphnia magna*)	Triclosan % purity unknown	LOEC = <0.1388 NOAEC = N.R.	No (supplemental) - 21-day test duration - static renewal test system - growth not measured as a chronic endpoint - % a.i. not given - raw data missing - concentration analysis insufficient	437407-01

No fathead minnow study has been submitted. The study on the waterflea does not fulfill the guideline requirement for a chronic aquatic invertebrate study (OPPTS 850.1300).

C. 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 fate data which may be required. (See triclosan environmental fate chapter and comments above on potential data requirements). However,

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. 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).

Table 6. Toxicity of Triclosan to Aquatic Plants

Species	Chemical, % Active Ingredient (a.i.) Tested	Endpoint (mg/L)	Satisfies Guidelines/ Comments	Reference (MRID No.)
Marine Diatom (*Skeletonema costatum*)	Triclosan 99.5%	EC_{50} = >0.066 NOEC = 0.0126	Yes (core) - 96-hour test duration - static test system	444228-01
Freshwater Diatom (*Navicula pelliculosa*)	Triclosan 99.5%	EC_{50} = 0.016 NOEC = 0.005	Yes (core) - 96-hour test duration - static test system	444228-01
Bluegreen Cyanobacteria (*Anabaena flos-aquae*)	Triclosan 99.5%	EC_{50} = 0.0012 NOEC = N.R.	Yes (core) - 96-hour test duration - static test system	444228-01
Duckweed (*Lemna gibba*)	Triclosan 99.5%	EC_{50} = >0.0625 NOEC = 0.0125	Yes (core) - 7-day test duration - static test system	444228-01

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.

II. Risk Assessment and Characterization

The triclosan uses that EPA regulates are classified as "indoor" uses. An ecological risk assessment is not typically conducted for the types of uses registered for triclosan. However, since triclosan has been detected in natural waters (see triclosan environmental fate chapter), EPA has performed a qualitative environmental risk assessment using monitoring levels of triclosan found in waterways and toxicity values from the tables in section I to develop risk quotients (RQs) and compare them to levels of concern (LOCs) for triclosan.

A. Environmental Fate Assessment Summary

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 transformation product has been identified, DCP (2,4-dichlorophenol), which was a maximum of 93.8-96.6% of the applied 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.

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.

Of the published literature studies on the occurrence of triclosan in waste water treatment plants, treatment plant efficiency, and open water measurements of triclosan, the majority suggest that aerobic biodegradation is one of the major and most efficient biodegradation pathways (70-80%) through which triclosan and its by-products are removed from the aquatic environment, with actual efficiencies ranging from 53-99% (Kanda *et al*., 2003) in activated sludge plants, and trickle down filtration ranging from 58-86% (McAvoy *et al*., 2002). Another pathway of removing triclosan from water in wastewater treatment plants is through the sorption of triclosan and associated by-products to particles and sludge (10-15%) because of the chemical's medium

to high hydrophobicity. Benchtop fate testing of triclosan found that 1.5-4.5% was sorbed to activated sludge and 81-92% was biodegraded (Federle *et al*., 2002).

B. Environmental Exposure and Qualitative Environmental Risk Assessment

Risk assessment integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. One method of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic:

RQ = EXPOSURE/TOXICITY

RQs are then compared to levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute** - the potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification; (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification; (3) **acute endangered species** - the potential for acute risk to endangered species is high, and regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, and regulatory action may be warranted, (5) **non-endangered plant risk** – potential for effects in non-target plants, and (6) **endangered plant risk** – potential for effects in endangered plants. Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to birds or mammals.

The ecotoxicity test values (measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: (1) LC_{50} (fish and birds), (2) LD_{50} (birds and mammals), (3) EC_{50} (aquatic plants and aquatic invertebrates) and (4) EC_{25} (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOAEC (birds, fish, and aquatic invertebrates), and (2) NOAEC (birds, fish and aquatic invertebrates). For birds and mammals, the NOAEC generally is used as the ecotoxicity test value in assessing chronic effects, although other values may be used when justified. However, the NOAEC is used if the measurement endpoint is production of offspring or survival.

Risk presumptions, along with the corresponding RQs and LOCs are tabulated below.

Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds and Wild Mammals		
Acute Risk	EEC[1]/LC50 or LD50/sqft[2] or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOAEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{\text{mg/ft}^2}{\text{LD50 * wt. of bird}}$ [3] $\frac{\text{mg of toxicant consumed/day}}{\text{LD50 * wt. of bird}}$

Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC[2] or NOAEC	1

[1] EEC = (ppm or ppb) in water

[2] MATC = maximum allowable toxicant concentration

Risk Presumptions for Plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute Risk	EEC/EC25	1
Acute Endangered Species	EEC/EC05 or NOAEC	1
Aquatic Plants		
Acute Risk	EEC[1]/EC50	1
Acute Endangered Species	EEC/EC05 or NOAEC	1

1 EEC = (ppb/ppm) in water

Risk Quotients – Based On Published Literature, Submitted Data, and USGS Monitoring Data

Triclosan was found in approximately 36 US streams (Kolpin et al., 2002), where effluent from activated sludge waste water treatment plants, trickle down filtration, and sewage overflow are thought to contribute to the occurrence of triclosan in open water. For this study, the U.S. Geological Survey surveyed a network of 139 streams across 30 states during 1999 and 2000. The selection of sampling sites was biased toward streams susceptible to contamination (i.e. downstream of intense urbanization and livestock production). The median concentration of triclosan was 140 ng/L and the maximum concentration detected was 2300 ng/L (Kolpin *et al*., 2002). Discharge into U.S. surface waters has resulted in other researchers finding triclosan from the low ng/L levels to a maximum of 2.3 µg/L (U.S. EPA, 2007).

From the toxicity tables in section I above, the highest toxicity in an acceptable fish study was achieved in a study on the rainbow trout (*Oncorhynchus mykiss*). The LC_{50} value obtained in this study was 0.288 mg/L (MRID 439693-01). 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 cannot be assessed. The highest toxicity in an acceptable aquatic plant toxicity study was achieved in a study on the bluegreen cyanobacteria (*Anabaena flos-aquae*). The EC_{50} value obtained in this study was 0.0012 mg/L and no NOEC was reported (MRID 444228-01).

For aquatic animals the LOC ranges from 0.05 for endangered species to 1 for chronic risks. Comparing the maximum concentration of triclosan found in U.S. surface waters (2.3 µg/L or 0.0023 mg/L) to the highest toxicity found in a fish acute study (0.288 mg/L), an RQ of 0.008 is obtained. This is less than all LOCs for aquatic animals and therefore the potential for triclosan to cause adverse effects on fish is not high.

For aquatic plants the LOC is 1. Comparing the maximum concentration of triclosan found in US streams (2.3 µg/L or 0.0023 mg/L) to the highest toxicity found in aquatic plants (0.0012 mg/L), an RQ of 1.92 is obtained. This is higher than the LOC and therefore the potential for acute risk to aquatic plants from triclosan exists. An evaluation of the effects of triclosan on natural freshwater algae located above and below a wastewater treatment plant indicates that a concentration of 0.00015 mg/L caused a significant reduction in *Chlamydomonas sp*. (RQ of 15.33). This is considered supplemental data, but points to the need for further research on shifts in algal communities, reductions in biomass, and effects on higher trophic levels (Wilson et al., 2003). A meta-analysis of literature, plus exposure modeling were 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. The exposure

models used in this study (GREAT-ER and PhATE) have not been peer reviewed by the Agency (Capdevielle et al., 2008).

The triclosan degradation product methyl triclosan was studied by the National Oceanic and Atmospheric Administration's (NOAA) Hollings Marine Laboratory to assess it's toxicity to the estuarine organisms grass shrimp (*Paleamonetes pugio*), bioluminescent bacterium (*Vibrio fischeri*), and the phytoplankton *Dunaliella tertiolecta*. Methyl triclosan is believed to be more persistent in the environment that its parent and have a higher potential to bioaccumulate since it is more lipophilic. However, mechanisms of transformation (and subsequent uptake) if by microbes in the gut or in the seawater, are unclear (DeLorenzo et al, 2007). Uncertainties exist as to the potential for triclosan degradates to contribute to acute and/or chronic impacts on aquatic organisms and ecosystems.

Risk Quotients – Based On Consumer Environmental Modeling

For a full discussion of the assumptions, approaches, and techniques used in the Agency's (consumer) environmental modeling effort for triclosan, the reader is referred to the attached Appendix (**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 environmental fate chapter for triclosan. These documents discuss in detail how the Agency performed this modeling effort. Thus, for brevity only the conclusions of this consumer environmental modeling will be presented here.

Consumer Environmental Modeling Results: As outlined in the attached Appendix, the Agency performed screening level environmental modeling and concluded that, if ***all of the triclosan produced annually for antimicrobial uses is released to surface water as a result of consumer uses***, then:[2]

- **Aquatic Animals**: Estimated concentrations of triclosan in surface water do not exceed concentrations of concern for acute risk presumptions for aquatic animals. (*See Appendix, Table 2*.)

- **Aquatic Animals**: Estimated concentrations of triclosan in surface water do not exceed concentrations of concern for endangered species risk presumptions for aquatic animals. (*See Appendix, Table 3*.)

- **Aquatic Vascular Plants**: Estimated concentrations of triclosan in surface water do not exceed concentrations of concern for endangered species risk presumptions for aquatic

2 As discussed in the revised triclosan environmental fate chapter, 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, EPA also concludes that chronic aquatic risks are unlikely from consumer uses of triclosan-treated plastic and textile items.

vascular plants (e.g., duckweed, *Lemna gibba*). (*See Appendix, Table 4*.)

- **Aquatic Non-Vascular Plants**: Estimated concentrations of triclosan in surface water do exceed concentrations of concern for acute risk presumptions for species that represent non-vascular freshwater plants (i.e., algae). The number of days of exceedance of the concentration of concern is 1 day for blue-green algae, 5 days for green algae, and 57 days for *Chlamydomonas sp.* (*See Appendix, Table 4*.)

Adjustments to Consumer Environmental Modeling Results: As indicated above, the Agency performed this environmental modeling in an effort to estimate:

(1) Concentrations of triclosan in surface water [from antimicrobial uses of triclosan (e.g., triclosan-treated plastic and textile items in households) to which aquatic organisms may be exposed as a result of potential releases of triclosan from these consumer uses; and

(2) Number of days per year that the concentration of triclosan in surface water exceeds the concentration of concern for aquatic organisms.

A critical assumption in this screening level, modeling analysis was that ***all of the triclosan produced annually for antimicrobial uses is released to surface water as a result of consumer uses***. That is, 100 % of all triclosan produced annually is released into household wastewater during washing and rinsing of products treated with triclosan as a materials preservative or as a functional component.

However, in an effort to check this 100 % release value used above for consumer scenarios, EPA reexamined available textile leaching data and determined that the 100 % assumption (for release of triclosan into household wastewater) is highly unlikely. Specifically, available data for textile leaching of triclosan indicate that triclosan leaches from a variety of fabrics in the range of 0.00 % to 0.55 %.[3]

Conclusions Based On Adjusted Consumer Environmental Modeling Results: Considering the above textile leaching data, one can reduce all calculations (for estimated triclosan concentrations and concentrations of concern) presented in the attached Appendix by a factor of 100. In doing so, EPA concludes that for aquatic animals and plants (vascular and non-vascular), estimated concentrations of triclosan in surface water do not exceed concentrations of concern for acute risk presumptions for any of these organisms. **What this means is that the 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.**

3 EPA assumes that leaching values for plastic are of the same magnitude as for textile products. Note that the Agency used the 0.55 % leaching value in its evaluation for children who may mouth (incidental oral ingestion) plastic items (e.g., toys).

Risk Quotients – Industrial Use Scenarios (e.g., Triclosan Incorporation Into Plastics or Textiles In Industrial Setting)

As discussed in the revised environmental fate chapter, 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 registrants perform environmental modeling and monitoring to address this issue. Until EPA receives these data we are unable to calculate risk quotients specific to these industrial scenarios.

C. Endangered Species Considerations

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

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

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment.

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.[4] 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. **An endangered species effect determination will not be made at this time.**

III. Confirmatory Data Required:

Environmental modeling and monitoring specific to plastic and textile facilities, where triclosan is incorporated into these items, is required. The registrant is 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 registrant must submit a protocol to the Agency for approval.

The available published literature indicates the potential for triclosan to bioconcentrate and bioaccumulate in the environment. In order to better characterize this, the Agency is requiring the following four studies:

1) Oyster bioconcentration study – BCF (850.1710) [Technical Grade Active Ingredient (TGAI)] or Pure Active Ingredient, Radio-Labeled (PAIRA);
2) Fish bioconcentration study – BCF (850.1730) (TGAI or PAIRA);
3) Chironomid sediment toxicity test (850.1790) (TGAI or PAIRA); and
4) Aquatic food chain transfer test (850.1850) (TGAI or PAIRA).

Prior to beginning these four studies the registrant must submit protocols to the Agency for approval.

Additionally, depending upon the results of the modeling and monitoring effort and the above four studies, the following ecological effects data may be required:

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) Oyster bioconcentration study – BCF (850.1710) (major degradate/metabolite of

4 The Agency is making this statement because published literature indicates that triclosan and triclosan transformation products are being detected in various environmental components and there are outstanding environmental modeling and monitoring data. (Also, see revised triclosan environmental fate chapter).

triclosan – e.g., methyl triclosan);
9) Fish bioconcentration study – BCF (850.1730) (major degradate/metabolite of triclosan – e.g., methyl triclosan);
10) Chironomid sediment toxicity test (850.1790) (major degradate/metabolite of triclosan – e.g., methyl triclosan);
11) Aquatic food chain transfer (850.1850) (major degradate/metabolite of triclosan – e.g., methyl triclosan);
12) Acute sediment toxicity to freshwater invertebrates (850.1735) (TGAI);
13) Acute sediment toxicity to estuarine invertebrates (850.1740) (TGAI);
14) Chronic sediment toxicity to freshwater and/or estuarine invertebrates (no guideline number) (TGAI); and
15) Additional plant toxicity testing: an additional algal toxicity test (850.5400) with the freshwater green alga, *Selenastrum capricornutum* (TGAI); and studies on the rooted freshwater macrophyte, rice (*Oryza sativa*) – 850.4225 and 850.4250 (2 tests on seedling emergence and vegetative vigor) (TEP).

IV. Label Hazard Statements for Terrestrial and Aquatic Organisms:

Triclosan labels must state:

"This pesticide is toxic to fish and aquatic invertebrates."

"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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authorities are 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."

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Appendix:

Estimates Of Exposures And Risks To Aquatic Organisms From Releases Of Triclosan To Surface Water As A Result Of Uses Under EPA'S Jurisdiction

[NOTE: Confidential Business Information (CBI) has been removed from this document]

ESTIMATES OF EXPOSURES AND RISKS TO AQUATIC ORGANISMS FROM RELEASES OF TRICLOSAN TO SURFACE WATER AS A RESULT OF USES UNDER EPA'S JURISDICTION[5]

INTRODUCTION

The Regulatory Management Branch II of the Antimicrobials Division (AD) requested the Risk Assessment and Science Support Branch (RASSB) of AD to provide estimates of exposures and risks to aquatic organisms from surface water releases of triclosan from uses under EPA's jurisdiction. Triclosan is regulated by both the U.S. Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA). The EPA regulates the antimicrobial uses of triclosan when used as a bacteriostat, fungistat, mildewistat, and deodorizer. The FDA-registered uses of triclosan include hand soaps, toothpaste, deodorants, laundry detergent, fabric softeners, facial tissues, antiseptics for wound care, and medical devices. General categories of antimicrobial uses of triclosan include use in commercial, institutional, and industrial premises and equipment; residential and public access premises; and as a materials preservative. Specific information on the use profile for triclosan used as an antimicrobial pesticide is posted on EPA's website at http://www.epa.gov/oppsrrd1/REDs/factsheets/triclosan_fs.htm. Some common specific uses of triclosan include its use as a materials preservative in textiles and plastics.

METHODOLOGY AND SCOPE OF THIS ANALYSIS

The Antimicrobials Division of EPA evaluates exposures and risks to aquatic organisms from releases of antimicrobial pesticides to surface water. Antimicrobial pesticides may potentially be released to surface water during their manufacture, processing, industrial use, commercial use, and consumer use. The Exposure and Fate Assessment Screening Tool, Version 2.0 (E-FAST 2) developed by EPA/OPPTS/OPPT is a screening-level computer tool that is used to estimate concentrations of a chemical in surface water to which aquatic organisms may be exposed as a result of these releases. The data and tools needed to estimate exposure to aquatic organisms from releases of a chemical to surface water from manufacture, processing, industrial use, and commercial use are different from those needed to estimate exposures to aquatic organisms from consumer use. The general population and ecological exposures from industrial uses module of E-FAST 2 is used to estimate exposure to aquatic organisms from releases of a chemical to surface water from manufacture, processing, industrial use, and commercial use. The Down-the-Drain module of E-FAST 2 is used to estimate exposure to aquatic organisms from releases of a chemical to surface water from consumer use.

Data Required for the General Population and Ecological Exposures Module

Analysis of exposures to aquatic organisms from releases of chemicals to surface water from manufacture, processing, industrial use, and commercial use requires data including: (1) the amount of chemical released on a daily basis to surface water from each facility that discharges

5 NOTE: Confidential Business Information (CBI) has been removed from this document.

the chemical of concern; (2) the location of facilities that discharge the chemical of concern to surface water or if that information is not available, the representative Standard Industrial Classification (SIC) code for facilities that discharge the chemical of concern to surface water; (3) the number of days of release per year for each facility or facility classification that discharges the chemical of concern; (4) the number of industrial facilities releasing the chemical of concern to surface water; and (5) concentrations of the chemical of concern to aquatic organisms. The ChemSteer model developed by OPPT or an approach based on this model can be used to estimate the amount of chemical released to surface water for each day of discharge for each discharge site. This information, along with the other input parameters delineated above can be used to run the general population and ecological exposures from industrial uses module of E-FAST 2.

Data Required for the Down-the-Drain Module

Analysis of exposures to aquatic organisms from releases of chemicals to surface water from consumer use requires data including: (1) an estimate of the wastewater treatment plant influent volume; (2) the percent removal of the chemical during wastewater treatment; and (3) concentrations of the chemical of concern to aquatic organisms. These input parameters are used to run the Down-the-Drain module of E-FAST 2.

Approach for Estimating Exposures from Down-the-Drain Releases

For this screening level analysis of exposures to aquatic organisms from uses of triclosan under EPA's jurisdiction, a simplifying assumption is that all of the triclosan under EPA's jurisdiction is released to surface water as a result of consumer uses. Estimates of exposures to aquatic organisms from releases to surface water from its manufacture, processing, industrial use, and commercial use are therefore, assumed to be negligible. Releases of triclosan to surface water from consumer uses are assumed to result entirely from disposal of consumer products into household wastewater. Triclosan is assumed to be released into household wastewater during washing and rinsing of products treated with triclosan as a materials preservative or other functional component. For this analysis, AD used the Down-the-Drain module of E-FAST to provide screening-level estimates of potential exposures and risks to aquatic organisms from releases to household wastewaters from consumer uses of triclosan.

The methodology for the Down-the-Drain module assumes that household wastewater undergoes treatment at a local wastewater treatment plant and that treated effluent is subsequently discharged into surface waters. The Down-the-Drain module provides estimates of exposure to aquatic organisms and exposure to humans from ingestion of drinking water and fish that may be exposed to these household wastewater releases. In addition, there is a probabilistic dilution model (PDM) option that provides estimates of the number of days per year that the concentration of a chemical in surface water exceeds the concentration of concern for aquatic organisms.

This analysis focused on exposure of aquatic organisms to triclosan and did not consider potential exposure to humans from ingestion of drinking water and fish contaminated with

triclosan. The PDM option of the Down-the-Drain module was used to estimate the number of days of exceedance of concentrations of concern for aquatic organisms downstream of waste water treatment plants (WWTPs). Input parameters needed to run the Down-the-Drain module of E-FAST 2 include: (1) the wastewater treatment plant (WWTP) influent volume of the chemical; (2) the percent of chemical removed during wastewater treatment; (3) the bioconcentration factor (BCF) of the chemical in fish; and (4) the duration of exposure. These last two input parameters are used to estimate exposure to humans from ingestion of drinking water and fish and are not used to estimate potential exposures to aquatic organisms. Table 1 presents data for input parameters used to run the Down-the-Drain module of E-FAST 2.

TABLE 1- INPUT DATA FOR THE DOWN-THE-DRAIN MODULE OF E-FAST 2	
WWTP Influent Volume (kg/yr)	***Value removed***
Bioconcentration Factor in Fish (BCF)	***Value removed***
Percent WWTP removal of Triclosan	***Value removed***
Exposure duration (years of use)	***Value removed***

The percent of chemical removed during wastewater treatment was assumed to be (***Value removed***) percent. Measurements reported from benchtop fate testing indicated that 81-92 percent of triclosan was biodegraded (Federle et al., 2002). There is also potential for triclosan undergoing wastewater treatment to adsorb to sludge and other solids. After a review of available literature and modeling results regarding the environmental fate of triclosan during wastewater treatment, (***… rest of statement removed…***). Companies that manufacture and import triclosan reported annual volumes for uses under EPA's jurisdiction to be (***… rest of statement removed…***). As a simplifying assumption, all of the triclosan reported to be produced or imported for uses under EPA's jurisdiction was assumed to enter the influent of wastewater treatment plants that receive household wastewaters.

For the PDM option of the Down-the-Drain module, values of the concentrations of triclosan of concern to aquatic organisms were selected for acute and endangered species risk presumptions for aquatic animals and plants using acute toxicity endpoint values for species intended to represent freshwater fish, freshwater invertebrates, and aquatic plants. For the acute risk presumption for aquatic animals, the concentration of concern was calculated by multiplying the estimated surface water concentration of triclosan by 0.5. For the endangered species risk presumption for aquatic animals, the concentration of concern was calculated by multiplying the estimated surface water concentration of triclosan by 0.05. For the acute and endangered species risk presumptions for aquatic plants, the concentration of concern was assumed to be equal to the estimated surface water concentration for triclosan. The measurement endpoint used for the acute risk presumption for aquatic plants is the EC_{50}. The measurement endpoint used for the endangered species risk presumption for aquatic plants is the NOAEC. Estimates of the number of days of exceedance of concentrations of concern for aquatic organisms downstream of waste water treatment plants were generated for both high-end and average case scenarios.

The Down-the-Drain module of E-FAST 2 provides both high-end time-averaged surface water concentrations and median time-averaged surface water concentrations of a chemical

released by a wastewater treatment facility receiving household wastewater. The high-end scenario uses surface water concentrations based on the 10th percentile stream dilution factor for streams to which wastewater treatment facilities that receive household wastewaters discharge. The average case scenario uses surface water concentrations based on the 50th percentile stream dilution factor for streams to which wastewater treatment facilities that receive household wastewaters discharge. A stream dilution factor is calculated by dividing the flow that represents the receiving stream flow downstream of a wastewater treatment plant by the wastewater treatment plant effluent flow. The stream flow data and stream dilution factors are ranked and the results are reported in terms of percentiles of the distribution of data. To estimate potential acute and chronic aquatic life impacts, the PDM option uses 1Q10 and 7Q10 stream flows. The 1Q10 is the lowest flow for a single day during any 10-year period. The 7Q10 is the lowest consecutive 7-day average flow during any 10-year period. Estimates for a high-end scenario are based on the averaged probability of exceedance of the 10 percent of WWTPs that have the highest probability of exceedance of the COC following treatment based on the estimated typical daily per capita wastewater volume released. Estimates for an average case scenario are based on WWTPs that have an average probability of exceedance of the COC following treatment based on the estimated typical daily per capita wastewater volume released.

AQUATIC EXPOSURE AND RISK ASSESSMENT

Results of the assessment of exposure and risk to aquatic organisms from uses of triclosan under EPA's jurisdiction that are disposed in household wastewaters entering wastewater treatment plants are presented for acute risk presumptions for aquatic animals; endangered species risk presumptions for aquatic animals; and acute and endangered species risk presumptions for aquatic plants. Table 2 presents concentrations of concern for acute risk presumptions for aquatic animals and the corresponding numbers of days of exceedance for these levels of concern based on high-end and average case scenarios. When using the PDM option of E-FAST 2, EPA/OPPT considers risks to be significant if the acute toxicity value for the most sensitive freshwater fish or invertebrate tested exceeds the concentration of concern in surface water for 4 days or more. Estimated concentrations of triclosan in surface water did not exceed concentrations of concern for acute risk presumptions for aquatic animals.

TABLE 2 – NUMBER OF DAYS EXCEEDANCE OF CONCENTRATIONS OF CONCERN FOR ACUTE RISK PRESUMPTIONS FOR AQUATIC ANIMALS

Test Species	Measurement Endpoint (mg/L)	Concentration of Concern (ug/L)	Basis of Concentration of Concern	High-End Scenario (# days COC exceeded)	Average Scenario (# days COC exceeded)
Rainbow trout (*Oncorhynchus mykiss*)	freshwater fish acute LC_{50} = 0.288	144	Core data from OPP guideline study	0	0

TABLE 2 – NUMBER OF DAYS EXCEEDANCE OF CONCENTRATIONS OF CONCERN FOR ACUTE RISK PRESUMPTIONS FOR AQUATIC ANIMALS					
Test Species	Measurement Endpoint (mg/L)	Concentration of Concern (ug/L)	Basis of Concentration of Concern	High-End Scenario (# days COC exceeded)	Average Scenario (# days COC exceeded)
Cladoceran (*Ceriodaphnia dubia*)	freshwater invertebrate acute EC_{50} = 0.13	65	EPA Office of Water (U.S. EPA, 2007	0	0
Waterflea (*Daphnia magna*)	freshwater invertebrate acute EC_{50} = 0.39	195	Supplemental data from OPP study that does not meet guideline requirements	0	0

Table 3 presents concentrations of concern for endangered species risk presumptions for aquatic animals and the corresponding numbers of days of exceedance for these levels of concern based on high-end and average case scenarios. Estimated concentrations of triclosan in surface water did not exceed concentrations of concern for endangered species risk presumptions for aquatic animals.

TABLE 3 – NUMBER OF DAYS EXCEEDANCE OF CONCENTRATIONS OF CONCERN FOR ENDANGERED SPECIES RISK PRESUMPTIONS FOR AQUATIC ANIMALS					
Test Species	Measurement Endpoint (mg/L)	Concentration of Concern (ug/L)	Basis of Concentration of Concern	High-End Scenario (# days COC exceeded)	Average Scenario (# days COC exceeded)
Rainbow trout (*Oncorhynchus mykiss*)	freshwater fish acute LC_{50} = 0.288	144	Core data from OPP guideline study	0	0
Cladoceran (*Ceriodaphnia dubia*)	freshwater invertebrate acute EC_{50} = 0.13	65	EPA Office of Water (U.S. EPA, 2007	0	0

TABLE 3 – NUMBER OF DAYS EXCEEDANCE OF CONCENTRATIONS OF CONCERN FOR ENDANGERED SPECIES RISK PRESUMPTIONS FOR AQUATIC ANIMALS					
Test Species	Measurement Endpoint (mg/L)	Concentration of Concern (ug/L)	Basis of Concentration of Concern	High-End Scenario (# days COC exceeded)	Average Scenario (# days COC exceeded)
Waterflea (*Daphnia magna*)	freshwater invertebrate acute EC_{50} = 0.39	195	Supplemental data from OPP study that does not meet guideline requirements	0	0

Table 4 presents concentrations of concern for acute risk presumptions for aquatic plants and the corresponding numbers of days of exceedance for these levels of concern based on high-end and average case scenarios. Note that measurement endpoints based on EC_{05} or NOAEC that could be used for endangered species risk presumptions for non-vascular freshwater plants were not available. However, a NOAEC value of 0.0125 mg/L based on core data from an OPP guideline study was available for a representative vascular aquatic plant species, the duckweed, *Lemna gibba*. This NOAEC value corresponds to a concentration of concern for triclosan in surface water of 12.5 ug/L. The PDM option of the Down-the-Drain module of E-FAST 2 predicted no exceedances of the concentration of concern for triclosan for endangered species risk presumptions for aquatic vascular plants..

Although estimated concentrations of triclosan in surface water were not predicted to exceed concentrations of concern for acute risk presumptions for species tested to represent vascular freshwater plants, concentrations of triclosan in surface water were predicted to exceed concentrations of concern for acute risk presumptions for species that represent non-vascular freshwater plants (i.e., algae). When using the PDM option of E-FAST 2, for the most sensitive algal species tested, if the concentration of concern is exceeded for 4 days or less, OPPT determines the potential for significant risk on a case-by-case basis. The number of days of exceedance of the concentration of concern is 1 day for blue-green algae, 5 days for green algae, and 57 days for *Chlamydomonas sp.* The concentration of concern of 0.15 ug/L for the algal species, *Chlamydomonas*, that was used to run the PDM option of the Down-the-Drain module of E-FAST 2 was based on findings of a significant reduction of this genera of algae based on an evaluation of the effects of triclosan on natural freshwater algae located above and below a wastewater treatment plant (Wilson et al. 2003). Although this evaluation is considered supplemental data, it indicates the need for additional investigation of shifts in algal communities, reductions in biomass, and effects on higher trophic levels (Wilson et al. 2003). Data on the high toxicity of triclosan to different types of algae and on concentrations of triclosan measured in surface waters indicate that the presence of triclosan in surface water at levels of concern to algae may have the potential to affect the structure and function of algal communities

in freshwater stream ecosystems, particularly immediately downstream of effluents from wastewater treatment facilities that treat household wastewaters. Significant adverse effects to aquatic algae, which are primary producers in aquatic ecosystems, might potentially impair or destroy the balance of aquatic ecosystems.

TABLE 4 – NUMBER OF DAYS EXCEEDANCE OF CONCENTRATIONS OF CONCERN FOR ACUTE RISK PRESUMPTIONS FOR AQUATIC PLANTS					
Test Species	Measurement Endpoint (mg/L)	Concentration of Concern (ug/L)	Basis of Concentration of Concern	High-End Scenario (# days COC exceeded)	Average Scenario (# days COC exceeded)
Chlamydomonas sp.	Concentration in freshwater that caused a significant reduction in this species is 0.00015	0.15	Supplemental data (Wilson et al. 2003)	57	6
Green algae (*Scenedesmus subspicatus*)	Non-vascular aquatic plant EC_{50} = 0.0007	0.7	EPA Office of Water (U.S. EPA 2007)	5	<1
Blue-green cyanobacteria (*Anabaena flos-aquae*)	Non-vascular aquatic plant EC_{50} = 0.0012	1.2	Core data from OPP guideline study	1	0
Duckweed (*Lemna gibba*)	Vascular aquatic plant NOAEC = 0.0125	12.5	Core data from OPP guideline study	0	0