

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

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# **ESTIMATES OF EXPOSURES AND RISKS TO AQUATIC ORGANISMS FROM RELEASES OF TRICLOSAN TO SURFACE WATER AS A RESULT OF USES UNDER EPA'S JURISDICTION**<sup>1</sup>

## **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](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 the chemical of concern; (2) the location of facilities that discharge the chemical of concern to

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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.

WWTP Influent Volume (kg/yr)	<i>Value removed</i>
Bioconcentration Factor in Fish (BCF)	<i>Value removed</i>
Percent WWTP removal of Triclosan	<i>Value removed</i>
Exposure duration (years of use)	<i>Value removed</i>

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<sub>50</sub>. 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 10<sup>th</sup> 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 50<sup>th</sup> 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 ( <i>Oncorhynchus mykiss</i> )	freshwater fish acute LC <sub>50</sub> = 0.288	144	Core data from OPP guideline study	0	0
Cladoceran ( <i>Ceriodaphnia dubia</i> )	freshwater invertebrate acute EC <sub>50</sub> = 0.13	65	EPA Office of Water (U.S. EPA, 2007)	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)
Waterflea ( <i>Daphnia magna</i> )	freshwater invertebrate acute EC <sub>50</sub> = 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 ( <i>Oncorhynchus mykiss</i> )	freshwater fish acute LC <sub>50</sub> = 0.288	144	Core data from OPP guideline study	0	0
Cladoceran ( <i>Ceriodaphnia dubia</i> )	freshwater invertebrate acute EC <sub>50</sub> = 0.13	65	EPA Office of Water (U.S. EPA, 2007)	0	0
Waterflea ( <i>Daphnia magna</i> )	freshwater invertebrate acute EC <sub>50</sub> = 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<sub>05</sub> 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.

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)
<i>Chlamydomonas sp.</i>	Concentration in freshwater that caused a significant reduction in this species is 0.00015	0.15	Supplemental data (Wilson et al. 2003)	57	6

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)
Green algae ( <i>Scenedesmus subspicatus</i> )	Non-vascular aquatic plant EC <sub>50</sub> = 0.0007	0.7	EPA Office of Water (U.S. EPA 2007)	5	<1
Blue-green cyanobacteria ( <i>Anabaena flos-aquae</i> )	Non-vascular aquatic plant EC <sub>50</sub> = 0.0012	1.2	Core data from OPP guideline study	1	0
Duckweed ( <i>Lemna gibba</i> )	Vascular aquatic plant NOAEC = 0.0125	12.5	Core data from OPP guideline study	0	0