

Environmental Safety of Select Antimicrobial Active Ingredients

Executive Summary

The environmental risks associated with two major active ingredients used in topical over the counter antimicrobial products (*i.e.*, triclosan (TCS) and triclocarban (TCC)) have been studied extensively in the scientific literature. Such studies have focused on both the aquatic and terrestrial environment. Screening level risk assessments has demonstrated risk for blue-green algae to TCS at the point of wastewater treatment plant outfall in limited circumstances. Risks are not likely for other endpoints for TCS and TCC.

Background

Risk is a function of exposure (likelihood of harm) and hazard (magnitude of intrinsic harm). High hazard with no exposure = no risk. All national and international environmental management systems for chemicals are based on risk assessments. Methods and models for the assessment of exposure (Predicted Environmental Concentration (PEC)) and hazard (Predicted No Effect Concentration (PNEC)) are being evaluated by the U.S. Environmental Protection Agency (EPA), the Organisation for Economic Co-operation and Development (OECD), and the European Union (EU), as well as a plethora of individual countries, to develop the most robust and feasible methods as possible that can generate consensus and acceptance among all stakeholders and to allow both economic growth and protection of the environment at the same time with sustainability as the ultimate aim. Technically, the environmental risk assessment is the PEC/PNEC comparison. This paper will very briefly summarize the state-of-the-science concerning the environmental risk of TCS and TCC. Since TCS and TCC have been appraised to have similar environmental properties (Halden & Paull, 2005a), they will be addressed simultaneously in this paper.

Terrestrial compartment

There is minimal exposure in the terrestrial environment to TCS (Federle *et al.*, 2002). This is presumably also true for TCC, according to the rationality of Halden & Paull (2005a). The primary source to this compartment is via application of biosolids (sewage sludge) from wastewater treatment plants since TCS and TCC are ingredients in household and personal care products with 'down-the-drain' disposal routes.

Multiple studies show substantial removal rates of TCC and TCS in activated sludge treatment systems (the most common method in the U.S.), with greater

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than 96% removal. Most of the removal is from biodegradation with only a small amount being adsorbed to biosolids (<4%). (Federle *et al.*, 2002; McAvoy *et al.*, 2002; TCC Consortium, 2002). As a consequence, only small amounts reach the surface water (Thomas & Foster, 2005; Kolpin *et al.*, 2004; TCC Consortium, 2002). The half-life of TCS in three experimental soils was calculated to be in the range of 17.4 to 35.2 days (Samsøe-Petersen *et al.*, 2003; Ciba, 2003). Another study found that TCC is biodegradable with a 50% mineralization rate of 10 hrs in biosolids (Gledhill, 1975; TCC Consortium, 2002). Furthermore, TCS was found to rapidly photodegrade in water by direct photolysis (half-life = 5 hr) (Latch *et al.*, 2005). It should be noted that application of biosolids (class B) on arable land where crops for human consumption are grown is not legal in the United States according to federal regulation 40 CFR 503 (<http://www.biosolids.org/docs/1index.PDF>). Overall, the conclusion is that exposures to TCS and TCC are low for the terrestrial compartment (Federle *et al.*, 2002). A recent Danish terrestrial risk assessment of TCS was not conclusive due to insufficient data (Samsøe-Petersen *et al.*, 2003).

Aquatic compartment

The highest likelihood of environmental exposure to TCS and TCC is in the aquatic compartment via wastewater effluent (McAvoy *et al.*, 2002; Reiss *et al.*, 2002; TCC Consortium, 2002). Under worst-case conditions, the TCS concentrations in rivers across the US are a maximum of 2.3 µg/L with a median of 0.14 µg/L. For TCS, the most sensitive aquatic indicator species, the lethal concentration for 50% (LC50) = 180 µg/L according to a recent U.S. Geological Survey (USGS) survey (Kolpin *et al.*, 2002). As a follow-up, the USGS published a paper in 2004 (Kolpin *et al.*, 2004) where they looked at low, normal and high flow in US streams and found that TCS was only detectable at low flow (low dilution) in 10% of the streams; at normal flow and high flow TCS was not detected (reporting limit > 1 µg/L). At low flow, the maximum concentration was 0.14 µg/L (Kolpin *et al.* 2004). Thomas & Foster (2005) report an average of 0.049 (± 0.022) µg/L TCS in waste water treatment plant effluent.

Halden & Paull (2005a) report TCC concentrations of up to 6.75 µg/L. Halden & Paull's sites were not representative of US streams (Halden & Paull, 2005b) due to the streams being comprised of up to 99% raw sewage due to leaking sewer lines (Halden & Paull, 2004) and should thus not be used in a risk assessment context (Sanderson, 2005). The TCC Consortium (2002) found that in 113 streams across the US, the TCC concentration ranged < 0.001 to 0.228 µg/L.

Since different monitoring investigations will likely result in different measured concentrations depending on selection criteria and sample size, the U.S. EPA uses predictive models for assessment of environmental concentrations, where

all stakeholders have agreed upon the terms the model is built upon. In the US, that model is the E-FAST Exposure model.

With an annual TCC usage rate of 750 t/yr and a conservative 94% wastewater treatment removal rate for activated sludge treatment plants (TCC Consortium, 2002), the predicted median environmental TCC concentration in surface water = 0.0013 µg/L, and the high-end concentration = 0.017 µg/L (TCC Consortium, 2002). The waterflea *Ceriodaphnia dubia* is the most sensitive aquatic species to TCC, with a 21-day chronic No Observed Effect Concentration (NOEC) of 1.46 µg/L. The NOEC value (1.46 µg/L) would be associated with an assessment factor of 10 (since there are chronic data for three trophic levels), resulting in a predicted no effect concentration (PNEC) of 0.146 µg/L. The PEC/PNEC comparison at the high end concentration, 0.017/0.146 = 0.11, indicate no or low risk to the aquatic compartment to TCC. This indicates no risk to the aquatic compartment under realistic conditions, where the *Clean Water Act* of 1972 is followed and the wastewater treatment plant is operated according to guidelines.

The Danish EPA conducted a risk assessment of TCS in 2003 based on an algae study with acetone as a co-solvent where the NOEC = 0.5 µg/L yielding a PNEC = 0.05 µg/L. They found that TCS is not expected to cause effects in surface water unless discharges are from low technology plants to streams with low dilution (Samsøe-Petersen *et al.*, 2003).

Conclusions

One of the two main components of any environmental risk assessment, the prediction of NOECs, are based on standardized tests and are generally reliable, especially if conducted under Good Laboratory Practice (GLP). The NOEC values for TCS and TCC are widely accepted (Orvos *et al.*, 2002). However, the other side of the equation, the PEC, has been more contested recently (Halden & Paull, 2005a, Sanderson, 2005). It is obviously not feasible to sample thousands of rivers and streams year round. Hence, realistic worst-case exposure scenarios are used to prioritize monitoring efforts. Despite preliminary prioritization of sites, there would still be large variations, as the TCC Consortium (2002) showed in 113 US streams (< 0.001 to 0.228 µg/L). The pragmatic goal oriented solution is to rely on modeled exposure concentrations. In the US, the preferred model is the E-FAST model [$PEC_{\text{aquatic}} = \text{amount per yr}/365 \text{ days} \times \text{water usage per capita per yr} \times \text{total population} - \text{removal rate}$]. This yielded predicted TCC concentrations of 0.0013 to 0.017 µg/L and risk quotients less than 1 indicating no risk. The conclusions of the screening level risk assessment of TCC in 2002 have been endorsed by both the EPA and Environmental Defense (TCC Consortium, 2002).

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