What does this mean for me?

First, one must understand that urine concentrations do not directly correlate to plasma concentrations at the time that the sample is drawn. The triclosan found in urine samples is what the body naturally excretes and represents a “snapshot” in time of what was earlier a triclosan concentration in one’s plasma. What is measured in the urine is not a direct and immediate time correlate of plasma concentration but rather an historic picture.

Here is an explanation of what can be determined by such a study:

Based on the *European Scientific Committee on Consumer Products Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation* we conservatively estimate a worst case systemic exposure dose (SED) of 0.245 milligrams (mg) triclosan per kilogram body weight per day from the use of personal care products containing triclosan (up to 0.3% triclosan per product).

This gives daily SED of 14.7 mg triclosan and an estimated plasma concentration of ~5650 nanograms (ng) triclosan per day. Based on an estimated human plasma volume of 2.6 liters (14.7 mg/ 2.6 L plasma).

Based on pharmacokinetic information we can assume 80% of triclosan in the plasma is passed daily to urine, thus urine could contain 11.7 mg triclosan/day (14.7 x 0.8). Applying a standard glomerular filtration rate (passage through kidneys) and a standard urine formation rate of 1 ml urine/minute one could expect, under our worst case exposure level, about 1440 milliliters (ml) urine/day contain 11.7 mg triclosan which is equivalent to 8100 ng triclosan/ml.

The highest urine concentration measured in the Center for Disease Control (CDC) National Health and Nutrition Examination Survey (NHANES) was 3700 ng triclosan/mL. As you can see, this is not an exceptionally high concentration and, is well below that which could be expected from daily use of personal care products based on our worst case assumptions presented above.

Additionally, one can also rely on data from Ciba’s clinical study report conducted by Luecker and submitted to the US FDA in support of the approved over-the-counter drug uses, in which human volunteers given 6 daily doses of 15 mg triclosan orally, had urinary total-triclosan measured daily and from days 10 to 45 showed about 700 micrograms (µg) triclosan daily. Using an estimated 1440 ml urine/day volume this would be about 486 ng triclosan/ml in these subjects. A number much smaller than our worst case estimates of 8100 ng triclosan/ml urine. This means that much less triclosan was absorbed into the body under actual exposure conditions than estimated from our worst case calculations. This is why we call them “worst case” calculations.

The NHANES value of 3700 ng triclosan/ml urine does not appear to be greater than estimated from our conservative systemic exposure data.

Upon reviewing the NHANES data, there were only a few values above the 100 ng triclosan/ml value, clearly indicating that for the majority of those in the study there was little to no triclosan detected in their urine samples.

Based on the data available a human SED of 0.245 mg triclosan/kg body weight/day is a safe human dose. This dose level represents a Margin of Safety well in excess of 100, the minimum value to declare a substance safe for use (as set forth in the aforementioned EU SCCP Guideline). The lowest MoS for triclosan is 196 based on data from 2-year oral exposure studies with rats and the highest MoS is 306 based on data from 2-year oral exposure studies with hamsters, studies on file with the US FDA and US EPA.

The conclusions published by NHANES stated that the "concentrations of triclosan appeared to be highest during the third decade of life and among people with the highest household incomes." Isn't this the age group most likely to be concerned with bacteria around their homes and children? Could product pricing be related? Anti-gingivitis toothpastes are OTC drugs whereas regular toothpastes are cosmetics and have less regulatory oversight and would therefore be less expensive products.

It is not clear why NHANES would choose to look at levels of an FDA approved OTC drug as other OTC drugs were not included in their survey.

1 kg = 1000 grams (g)
1 g = 1000 mg
1 mg = 1000 µg
1 µg = 1000 ng

Click here to access the SCCP's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation.