



Kutol Update on Triclosan

There have been headlines in the news recently about the antibacterial agent Triclosan. Kutol uses Triclosan in many of our antibacterial soaps. Some consumer groups and one Congressman have raised questions about the safety of Triclosan. Kutol is monitoring the discussion on Triclosan. In today's politically charged atmosphere there are many issues about many ingredients and how they affect humans and the environment. We are trying to sort out the politics from the science.

If someone is concerned about the antibacterial agent Triclosan in particular we would offer the following information:

This is what the FDA says about Triclosan:

What consumers should *know*:

- Triclosan is not known to be hazardous to humans.
- FDA does not have sufficient safety evidence to recommend changing consumer use of products that contain Triclosan at this time.
- In light of questions raised by recent animal studies of Triclosan, FDA is reviewing all of the available evidence on this ingredient's safety in consumer products.
- FDA will communicate the findings of its review to the public in spring 2011.

What is known about the safety of Triclosan:

- Triclosan is not currently known to be hazardous to humans. Several scientific studies have come out since the last time FDA reviewed this ingredient that merit further review.
- Animal studies have shown that Triclosan alters hormone regulation. However, data showing effects in animals don't always predict effects in humans.
- Studies testing bacteria have raised the possibility that Triclosan contributes to making bacteria resistant to antibiotics.
- In light of these studies, FDA is engaged in an ongoing scientific and regulatory review of this ingredient. **FDA does not have sufficient safety evidence to recommend changing consumer use of products that contain Triclosan at this time.**

The above information is from:

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm205999.htm>

Currently the FDA has approved the use of Triclosan in many popular oral products like toothpaste manufactured by well known companies such as Colgate. We believe these products would be discontinued if there were immediate concerns by the FDA about the safe use of Triclosan. Also if the FDA allows the use of Triclosan in products that can be ingested we do NOT feel there is any hazard to people using a .5% Triclosan solution on their hands.

What the EPA says about Triclosan:

- The EPA performed consumer environmental modeling for Triclosan, which demonstrated that estimated concentrations of Triclosan in surface water do not exceed concentrations of concern for acute risk for aquatic organisms and plants.
- In 2008 EPA conducted a human health risk assessment for Triclosan to support the reregistration eligibility decision. EPA evaluated toxicology, product and residue chemistry, and occupational/residential exposure studies as well as available open literature and determined that the data are adequate to support the reregistration decision. EPA conducted these assessments using available animal studies. In its reregistration review, EPA considered all available data on Triclosan, including data on, endocrine effects, developmental and reproductive toxicity, chronic toxicity and carcinogenicity.
- EPA and FDA are collaborating on research projects that will help both agencies to better characterize the endocrine-related effects of Triclosan, including toxicological effects, human relevance, and the doses at which they occur to determine if levels of human exposure are safe or not. The agencies will pay close attention to this ongoing research and will amend the regulatory decision if the science supports such a change.
- The EPA will continue to participate in the Interagency Task Force on Antimicrobial Resistance and evaluate information that results from that activity, and will continue its cooperative efforts with the FDA to share information on Triclosan and discuss future research efforts and needs that will best meet the needs of the two agencies.

The above information is from: http://www.epa.gov/oppsrrd1/REDs/factsheets/triclosan_fs.htm

Bacterial Resistance:

Regarding the topic of bacterial resistance and Triclosan creating future strains that are resistant, Dr. Stuart Levy et al reported in a *Nature* article published in 1998 antibiotic resistance of bacteria could be shown to be caused by exposure to Triclosan. Since then, **no less than 7 published peer reviewed articles have been published that describe studies, which have demonstrated that Triclosan is not scientifically associated with bacterial resistance.** One such article published is *Antimicrobial Agents and Chemotherapy*, August 2004, p. 2973-2979, Vol. 48, No. 8 *co-authored by Dr Levy*

The above information is from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC478530/>

Summary

Most of the environmental concerns about Triclosan are generated by the in home or retail use of Triclosan containing products because of the large volume used by this market. Antibacterial agents by their very nature are designed to kill germs and therefore can have an effect on the environment. If someone is concerned about the use of antibacterial ingredients they should switch to a regular lotion soap that does NOT contain any antibacterial agents. Kutol recommends our Green Seal Certified soaps as products that contain no antibacterial agents and are deemed to be “environmentally friendly or Green”.

Based on the information Kutol has seen so far it is our belief that when the FDA finishes their review in the spring of 2011 we expect them to reaffirm their position of “no changes needed” especially with regard to changing any regulations when it comes to the use of Triclosan in the “away from home” soap market.

As noted above the FDA and EPA say Triclosan is not hazardous to humans and the FDA has sufficient safety evidence at this time to not recommend changing consumer use of products that contain Triclosan.

Until the FDA changes their regulations or opinions, we have no reason to change our use of Triclosan.

May 10, 2010