

Tampons and Asbestos, Dioxin & Toxic Shock Syndrome

July 23, 1999

FDA regulates the safety and effectiveness of medical devices, including tampons. Recently it has come to the agency's attention that allegations about tampons are being spread over the Internet. It is alleged that tampons are contaminated by asbestos and dioxin during manufacture, and that rayon fibers cause toxic shock syndrome (TSS). The available scientific evidence does not support these rumors. The following information will help answer concerns.

Asbestos Concerns

In the last six months, unfounded rumors on the Internet have suggested that U.S. tampon manufacturers add asbestos to their products to promote excessive menstrual bleeding in order to sell more tampons. FDA has no evidence of asbestos in tampons or any reports regarding increased menstrual bleeding following tampon use.

Before any tampon is marketed in the U.S., FDA reviews its design and materials. Asbestos is not an ingredient in any U.S. brand of tampon, nor is it associated with the fibers used in making tampons. Moreover, tampon manufacturing sites are subject to inspection by FDA to assure that good manufacturing practices are being followed. Therefore, these inspections would likely identify any procedures that would expose tampons products to asbestos. If any tampon product was contaminated with asbestos, it would be as a result of tampering, which is a crime. Thus far, FDA has received no reports of tampering. Anyone having knowledge of tampon tampering is urged to notify FDA or a law enforcement officer.

Dioxin and Rayon Concerns

There are also allegations that some tampons contain toxic amounts of the chemical dioxin. The term "dioxin" or "dioxins" actually refers to a number of related chemical compounds. State-of-the art testing of tampons and tampon materials that can detect even trace amounts of dioxin has shown that dioxin levels are at or below the detectable limit. No risk to health would be expected from these trace amounts.

Tampons currently sold in the U.S. are made of cotton, rayon, or blends of rayon and cotton. Rayon is made from cellulose fibers derived from wood pulp. In this process the wood pulp is bleached. At one time, bleaching the wood pulp was a potential source of trace amounts of dioxin in tampons, but that bleaching method is no longer used. Rayon raw material used in U.S. tampons is now produced using elemental chlorine-free or totally chlorine free bleaching processes. These methods for purifying wood pulp are described below:

- *Elemental chlorine-free bleaching* refers to methods **that do not use elemental chlorine gas** to purify the wood pulp. These methods include the use of chlorine dioxide as the bleaching agent as well as totally chlorine-free processes. Some elemental chlorine-free bleaching processes can theoretically generate dioxins at extremely low levels, and dioxins are occasionally detected in trace amounts in mill effluents and pulp. In practice, however, this method is considered to be dioxin free.
- *Totally chlorine-free bleaching* refers to use of bleaching agents that contain no chlorine. These methods are also dioxin-free. Totally chlorine-free methods include, for example, use of hydrogen peroxide as the bleaching agent.

The Environmental Protection Agency (EPA) has worked with wood pulp producers to promote use of dioxin-free methods because dioxin is an environmental pollutant. Because of decades of pollution, dioxin can be found in the air, water and ground. Therefore, while the methods used for manufacturing tampons today are considered to be dioxin-free processes, traces of dioxin may still be present in the cotton or wood pulp raw materials used to make tampons. Thus, there may be trace amounts of dioxin present from environmental sources in cotton, rayon, or rayon/cotton tampons.

When questions about dioxin arose a number of years ago, FDA asked tampon manufacturers to provide information about their pulp purification processes and the potential for dioxin contamination. Manufacturers of rayon tampons are also asked to routinely monitor dioxin levels in the raw material used or the finished tampons. Manufacturers have provided FDA with test results of studies conducted at independent laboratories, using the most sensitive test methods available. Dioxin monitoring is a highly technical assay performed at only a few independent expert laboratories in the U.S. The detectable limit of this assay is currently approximately 0.1 to 1 parts per trillion of dioxin.

Using these tests, dioxin levels in the rayon raw materials for tampons are reported to be at or below the detectable limit of the state-of-the-art dioxin assay, i.e., approximately 0.1 to 1 parts per trillion. FDA's risk assessment indicates that this exposure is many times less than normally present in the body from other environmental sources, so small that any risk of adverse health effects is considered negligible. A part per trillion is about the same as one teaspoon in a lake fifteen feet deep and a mile square. This is far below the threshold that EPA believes puts consumers at risk for cancer or other adverse effects.

Toxic Shock Syndrome (TSS)

There are also allegations that rayon in tampons causes TSS, and dryness or ulcerations of vaginal tissues.

TSS is a rare but potentially fatal disease caused by a bacterial toxin. (Different bacterial toxins may cause TSS, depending on the situation, but most often *streptococci* and *staphylococci* are responsible.) The number of reported TSS cases has decreased significantly in recent years. Approximately half the cases of TSS reported today are associated with

tampon use during menstruation, usually in young women. TSS also occurs in children, men, and non-menstruating women. In 1997, only five confirmed menstrually-related TSS cases were reported, compared with 814 cases in 1980 [according to data from the Centers for Disease Control and Prevention (CDC)]. Although scientists have recognized an association between TSS and tampon use, the exact connection remains unclear. Research conducted by the CDC suggested that use of some high absorbency tampons increased the risk of TSS in menstruating women. A few specific tampon designs and high absorbency tampon materials were also found to have some association with increased risk of TSS. These products and materials are no longer used in tampons sold in the U.S. Tampons made with rayon do not appear to have a higher risk of TSS than cotton tampons of similar absorbency.

Vaginal dryness and ulcerations may occur when women use tampons more absorbent than needed for the amount of their menstrual flow. Ulcerations have also been reported in women using tampons between menstrual periods to try to control excessive vaginal discharge or abnormal bleeding. Women may avoid problems by choosing a tampon with the minimum absorbency needed to control menstrual flow and using tampons only during active menstruation.

To help women compare absorbency from brand to brand, FDA requires that manufacturers measure absorbency using a standard method and describe absorbency on the package using standardized terms. Thus, the terms "junior," "regular," "super," and "super plus," always describe a specific range of tampon absorbency regardless of the brand.

FDA requires manufacturers to give information on the package labeling about the signs of TSS and how to minimize the risk. Women are encouraged to read this information before using tampons and to ask about TSS when getting a medical checkup. More information is available about this topic on the web at:

http://www.fda.gov/opacom/catalog/ots_tss.html