



# Parabens

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<b>Advisory Committee:</b>	Science and Technology / Infection Control
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## Overview

Parabens have been some of the most widely used preservatives since the mid 1920s in products such as cosmetics, pharmaceuticals and foods and have been officially permitted or approved for use as preservatives by key regulatory bodies around the world, including the U.S. FDA. Chemically, parabens are esters of p-hydroxybenzoic acid. The most common parabens used are methylparaben, propylparaben, and butylparaben. Any product containing water is susceptible to being spoiled by the growth of fungi or bacteria, causing problems such as unsightly mold growth, discoloration, malodor or breakdown of the product. Typically, more than one paraben is used in a product, and they are often used in combination with other types of preservatives to provide preservation against a broad range of microorganisms, both to maintain product integrity and more importantly to protect consumers. The use of mixtures of parabens allows the use of lower levels while increasing preservative activity.

## POSITION

The U.S. FDA has classified methyl and propylparaben as GRAS, which means they are Generally Regarded As Safe by medical and toxicological experts for use in preserving food. The FDA has also stated that Parabens are safe for use in cosmetics. The Cosmetic Ingredient Review (CIR) reviewed the safety of methylparaben, propylparaben, and butylparaben in 1984 and concluded they were safe for use in cosmetic products at levels up to 25%. On November 14, 2003, the CIR began the process to reopen the safety assessments of these parabens in order to offer interested parties an opportunity to submit new data for consideration. In September 2005, the CIR decided to re-open the safety assessment for parabens to request exposure estimates and a risk assessment for cosmetic uses. In December 2005, after considering the margins of safety for exposure to women and infants, the Panel determined that there was no need to change its original conclusion that parabens are safe as used in cosmetics.

Many materials found in plants used as food also have an estrogenic effect. These naturally occurring materials are called phytoestrogens and are present in soy and other fruits and vegetables such as blueberries, carrots, strawberries and peanuts. Some of these phytoestrogens, when tested in the same way as parabens, give similar estrogen-like results. However, Parabens have been shown to be 10,000 times weaker than the most potent phytoestrogens and 100,000 times less potent than estradiol, the estrogen produced naturally by the body. Most scientists agree that there is no endocrine-disrupting

effect from the use of parabens in cosmetic and personal care products because their action, if any, is extremely weak.

**Kleenhantz**® antimicrobial towelettes contain both methylparaben and propylparaben at levels well below those considered safe and acceptable for use on skin. Their purpose is to act as a preservative and helps to extend shelf life considering that the **Kleenhantz**® formula consists of over 99% water.

Parabens provide clear benefit by effectively protecting the product against the growth of potentially harmful microorganisms. Based on the weight of current scientific evidence, there is no reason for consumers to be concerned about the use of cosmetic and personal care products containing parabens.

### **References**

- U.S. Food and Drug Administration (Cosmetics, Parabens, updated October 31, 2007)
- CosmeticsInfo.org

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