

## CTFA Response Statement

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#### Safety of Parabens - Darbre Paper

The recent publication by Darbre et al., does not claim that parabens cause breast cancer. The authors note that the study is very preliminary. It is based on a small sample size with inconsistent results. For example, samples with no breast tissue at all were found to have levels of parabens as high as some of the samples with breast tissue, showing some unexplained contamination of the analytical procedure. Additionally, the amounts of parabens measured were in the nanogram range; exceedingly small amounts.

An additional confounding factor is the use of parabens, primarily methylparaben, to preserve many medicines, including those used to treat breast cancer. In fact, the paraben reported most frequently and at the highest concentration in this article was methylparaben. It has been tested for estrogenic potency and found to be negative. This fact undermines the authors' implication that all parabens are estrogenic and could lead to breast cancer.

The authors also do not provide supporting evidence that there could be a relationship between antiperspirants and deodorants, parabens, and breast cancer. In fact, the vast majority of the antiperspirant/deodorant formulations on the market do not need preservatives, such as parabens, and so do not contain them.

A wealth of data supports the safety of antiperspirants and parabens. A study reported in the Journal of the National Cancer Institute (JNCI), October 16, 2002, cites the work of researchers from the Fred Hutchinson Cancer Research Center and the University of Washington both in Seattle, Washington. Their extensive population-based case-control study concludes that **"These findings do not support the hypothesis that antiperspirant use increases the risk for breast cancer." The researchers also said that "there was no evidence" of risk for breast cancer from the use of deodorants.**

According to the American Cancer Society, there have been many extremely thorough epidemiological studies of breast cancer risk and they have not found antiperspirant use to be a risk factor for breast cancer.

The Food and Drug Administration (FDA) regulates cosmetics and nonprescription drugs to assure their safety. There is no evidence of harm from the use of deodorants or antiperspirants. They are safe and consumers should not be unnecessarily alarmed.

#### PARABENS

Parabens are a class of preservatives (ingredients that help to prevent microbial contamination) that have been used in a wide variety of foods, drugs, and cosmetics and keep products safe. Parabens have a long history of use in these products, and have been specifically recognized as safe by the U.S. Food and Drug Administration. Additionally, the Cosmetic Ingredient Review Expert Panel reviewed their use in cosmetics in 1984 and concluded that they were safe as used in cosmetics.

On November 14, 2003, as part of the normal re-review process, the CIR Expert Panel determined that it wanted to conduct a thorough review of the literature since the previous report in 1984 to decide if it was appropriate to reopen the safety assessment.

The Food, Drug, and Cosmetic Act requires that cosmetics and non-prescription drugs and their individual ingredients must be safe and that labeling must be truthful and not misleading. FDA can take immediate action to stop the sale of any product that does not meet its high

standards.

Given the oversight by FDA, commitment of the industry, and long history of safe use, consumers can have confidence in their cosmetics and non-prescription drugs.

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