

**Preservatives in cosmetology:
A review of parabens
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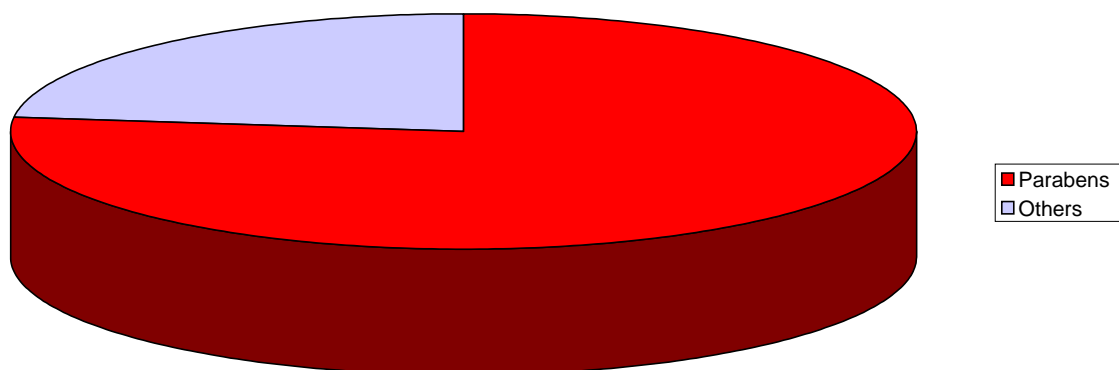
Translated from the French, published in the *Journal de Médecine Esthétique et de Chirurgie Dermatologique*, September 2006.

Parabens are the preservatives most commonly used in cosmetics, foods, and drugs (*Elder*, 1984). They have been the subject of numerous studies that have established not only their broad spectrum of action against numerous micro-organisms, but also their efficacy, stability, and their lack of side effects. Despite these studies, a controversy surrounding parabens has been mounting since 2004. As a result, the consumer is today demanding products that are paraben-free.

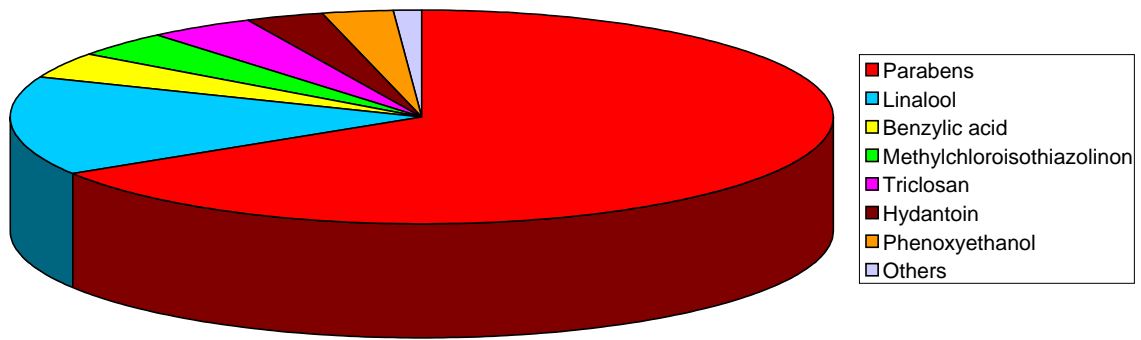
In the late 1990s, several studies suggested that parabens had an oestrogenic activity. Then, in 2004, English researchers detected traces of parabens in breast tumour tissue samples. The media seized the subject and widely diffused the news: parabens used in cosmetics, most notably in deodorants, could cause breast cancer. As a result, several cosmetic companies have recently altered their product formulae, replacing parabens with alternate preservative systems. It should be noted, however, that the cosmetic industry regulatory agencies, both European and American, continue to support the use of parabens and have recently reiterated that there is no epidemiologic evidence linking parabens to breast cancer.

Parabens: the facts

Parabens, or PARAHydroxyBENzoates, are used as preservatives in cosmetics, with methyl- and propylparaben being the most common (*Rastogi et al.*, 1995). Parabens are present in approximately 80% of cosmetics and are by far the most frequently used preservatives (Graph 1, 1995 and Graph 2, 2006; <http://membres.lycos.fr/leflacon/>).



Graph 1
Distribution of preservatives in cosmetic products in 1995



Graph 2
Distribution of preservatives in cosmetic products in 2006

Numerous studies have shown that parabens present several characteristics that make them the ideal preservative:

- They are stable and water soluble;
- They exert a broad spectrum antimicrobial effect;
- They are both bactericidal and fungicidal;
- They have a weak allergenicity and are non-irritating;
- They have a low toxicity.

Parabens have a minimal sensitizing effect on the skin: even individuals sensitive to parabens tolerate cosmetics containing parabens if these are applied to healthy skin (i.e. skin without eczema or other disease). Fisher called this phenomenon the “paraben paradox” and emphasized the fact that traumatized skin or eczema-prone skin is more sensitive to parabens than healthy skin as compared to other allergens applied topically (*Fisher, 1973*). *Hannuksela et al.* tested the allergenicity of parabens on individuals suffering from eczema over a period of three years: an allergy to parabens was detected in only 0.3% of the cases, versus a much higher incidence (3.6%) of allergies to other ingredients such as fragrances (*Hannuksela et al., 1976*).

Finally, it is important to note that the body of knowledge available on parabens is greater than that on most other preservative systems. Furthermore, seventy years of safe and successful usage further confirm the safety and efficacy profile of parabens.

Parabens: the fears

Routledge et al. (1998) were the first to propose that parabens have an intrinsic oestrogenic activity and the ability to activate in-vitro oestrogen receptors. A later study indicated that parabens’ oestrogenic activity is 10^4 to 10^7 times weaker than that of the main natural oestrogen, 17β -oestradiol, and increases with the size of the alkyl group; indeed, the detected activities of benzyl-, butyl-, propyl-, ethyl- and methylparabens are respectively 4,000, 8,000, 30,000, 200,000 and 3,000,000 times less important than that of 17β -oestradiol (*Miller et al., 2001*).

The initial controversy started by Routledge in the late 1990s nonetheless intensified in 2004 when *Darbre et al.* found traces of parabens in 18 out of 20 breast tumour tissue samples (*Darbre et al.*, 2004). In Darbre's study, parabens were extracted from breast tumour tissue samples and individual paraben molecules were identified, quantified, and compared to those present in a control group (obtained with the same procedures of extraction but without breast tumours). The average value of total parabens was 20.6ng/g of tissue in the breast tumour tissue samples. Methylparaben showed the highest value (12.8 ± 2.2 ng/g of tissue), accounting for 62% of total parabens. In contrast, benzylparaben was not detected. Parabens were found in higher concentrations in the breast tumour tissue samples than in the control samples, but the latter also contained considerable concentrations of parabens.

Even though the statistical analysis was not conclusive, the data was sufficient to question the use of parabens in cosmetic products. The media seized the subject, and through television reports, print articles, and online papers, scared consumers. In particular, it was published that cosmetic products applied near the breasts (e.g. deodorants) could locally increase the risk of breast cancer.

Criticisms of the fear

Darbre's study suffers from various flaws. First, the study is based on a small number of samples. Furthermore, the control samples were contaminated by parabens of an unknown source; the parabens discovered in the tumour samples could thus come from an external contamination rather than from the breast tumour tissue. The fact that no benzylparaben was found in the breast tumour tissue samples is questionable, as it is known for its relatively strong oestrogenic activity (4,000 times less important than 17β -oestradiol). Rather, it was methylparaben that was the most abundant paraben in the breast tumour tissue samples, despite the fact that its oestrogenic activity is relatively the weakest (3,000,000 times less important than 17β -oestradiol).

It thus seems essential to continue to investigate and study the link between parabens and breast tumour tissue before establishing final conclusions. However, there has been no further study published on the possible link between parabens and breast cancer since 2004. Finally, there is no sound scientific argument that establishes a connection between the unproven carcinogenicity of parabens and their skin sensitizing effect.

Current recommendations

Today, most scientists agree that there is no proven link between parabens and breast cancer, and even less of one between the use of cosmetic products containing parabens and breast cancer. Some – including Darbre! – even recommend the preferential use of methylparaben because of its weak oestrogenic activity and its reduced absorption through the skin (*Murrell and Vincent*, 1950; *Whitworth and Jun*, 1973; *Darbre et al.*, 2003).

The regulatory agencies have also spoken in favour of parabens. The Cosmetic Ingredient Review (CIR) Expert Panel published a report in December 2005 stating that after carefully reviewing the existing data on parabens, they found no evidence supporting a ban

(<http://www.cir-safety-org/>). Similarly, the Department of Evaluation of Cosmetic Products, Biocides and Tattoos arrived at the same conclusion and favours the continued use of methyl-, ethyl-, propyl- and butylparabens.

Some industry leaders have also continued to support the use of parabens. Most notably, Avon, which has long identified itself with the fight against breast cancer, stated in 2005 that parabens are safe and that replacing them with alternative preservative systems is what would pose a threat to women's health (<http://www.avon.com>).

The alternatives to parabens are indeed limited. More often than not, these are less effective, not well tolerated topically, and their safety has not been confirmed by adequate studies or long term use. Thus, replacing parabens by other, less well-known, preservative systems could present a higher consumer risk than parabens themselves.

Conclusion

The controversy surrounding parabens focuses on their alleged oestrogenic activity and potential carcinogenicity, and is based on a single study published in 2004. The fear of parabens nonetheless propagated quickly, leading consumers to ask for paraben-free products and manufacturers to embrace that demand. However, both scientists and industry regulatory agencies continue to agree that there is no clearly established epidemiologic link between parabens and breast cancer. It is the replacement of parabens by other, less-known, preservative systems that could present a consumer risk. It thus behoves industry leaders, scientists, medical doctors, and cosmetic experts to reassure consumers and to set the record straight about the safety and efficacy of parabens.

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