

Parabens: The 2019 Nonallergen of the Year

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Each year, the American Contact Dermatitis Society (ACDS) names an allergen of the year with the purpose of promoting greater awareness of a key allergen and its impact on patients. Often, the allergen of the year is an emerging allergen that may represent an underrecognized or novel cause of allergic contact dermatitis (ACD). In 2019, the ACDS chose parabens as the “nonallergen” of the year to draw attention to their low rate of associated ACD despite high public interest in limiting exposure to parabens.¹

What types of products contain parabens?

Parabens are preservatives commonly found in many different categories of personal care products. Preservatives inhibit microbial growth and are necessary ingredients in water-based products. The 4 most common parabens used in personal care products are methylparaben, ethylparaben, propylparaben, and butylparaben.¹ Parabens are metabolized to 4-hydroxybenzoic acid and are excreted in urine. When parabens are applied topically, there is minimal penetration through intact human skin.² In the United States, parabens are allowed as preservatives in cosmetics at concentrations up to 0.4% when used alone or up to 0.8% when used in combination with other parabens.³

Consumers are exposed to parabens in a wide variety of personal care products. The Contact Allergen Management Program (CAMP) is a system owned and managed by the ACDS that typically is used to generate lists of safe personal care products for patients and also can be queried for the presence of individual chemicals in products. According to a 2018 query of the CAMP, parabens were found in 19% of all products.¹ A more recent query of CAMP (<http://www.contactderm.org/resources/acds-camp>) in March 2019 showed parabens were present in 39.3% of makeup products, especially in eye products, foundations,

and concealers; parabens also were found in 34% of moisturizers, 11.5% of soaps, and 19% of sunscreens. Notably, 14.8% of prescription topical steroids listed in the CAMP contained a paraben. Another method for evaluating chemical contents of personal care products is a review of the Voluntary Cosmetic Registration Program, a US Food and Drug Administration–based registry for cosmetic products. Survey data from the Voluntary Cosmetic Registration Program in 2018 documented methylparaben in 11,626 formulations.⁴ Other parabens included propylparaben (8885 products), butylparaben (3915 products), and ethylparaben (3860 products). Parabens were reported more frequently in leave-on rather than rinse-off products.⁴

In medications, parabens are recommended at concentrations of no more than 0.1%.¹ Fransway et al¹ compiled a list of medications that contain parabens, including commonly prescribed dermatologic topical medications such as corticosteroids, several acne preparations, eflornithine, fluorouracil, hydroquinone, imiquimod, urea, and sertaconazole. Oral and parenteral medications including local anesthetics and corticosteroids also may contain parabens.

Consumers also may be exposed to parabens through foodstuffs. Methylparaben and propylparaben have been classified as generally recognized as safe in foods by the US Food and Drug Administration.⁵ The acceptable daily intake of parabens in food is 0 to 10 mg/kg of body weight,¹ and the estimated dietary intake for a typical adult is 307 mg/kg of body weight daily.⁶ Several studies on paraben content in foodstuffs have confirmed their presence in both natural and processed foods.^{1,6} Systemic contact dermatitis caused by ingestion of parabens is rare. In general, individuals with positive patch test reactions to parabens should not routinely avoid them in foods or oral medications,¹ but they should, of course, be avoided in topical medications.

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What is the rate of ACD with parabens?

One of the main reasons that parabens were designated as the ACDS nonallergen of the year is the very low rate of ACD associated with parabens. The North American Contact Dermatitis Group, a research group with members in the United States and Canada, reported a 0.6% positive reaction rate when patch testing with paraben mix 12%,⁷ which closely compares with a 0.8% positive reaction rate when patch testing with paraben mix 16% using the Mayo Clinic standard series.⁸ From the standpoint of ACD, this very low patch test reaction rate makes parabens one of the safest preservative options for use in cosmetic products.

Are there health risks associated with parabens?

The paraben controversy in the scientific literature and in the lay press centers around potential health risks and endocrine disruption. We will focus on the conversation regarding parabens and the risk for endocrine disruption and association with breast cancer.

Parabens have been reported to have estrogenic effects; however, the bulk of the data is limited to in vitro and animal studies, with less evidence of endocrine disruption in humans.² In vitro studies have demonstrated that the estrogenic potency of parabens is much less than that of estrogen. In one study, parabens were shown to be 10,000-fold less potent than 17 β -estradiol⁹; in a separate study, they had a maximum potency of only 1/4000 that of estrogen.¹⁰ Additionally, an in vitro study showed varying ability for parabens to bind estrogen receptors, with a greater ability to bind with longer alkyl side chains.¹¹ The result is decreased or increased estrogen activity, dependent on side chain length and type of receptor.² Finally, some studies add conflicting results that parabens may actually create an antiestrogenic effect in human breast cancer cells.¹² From the standpoint of estrogen mimicry, there are no known studies in humans confirming harmful effects associated with paraben exposure.

The reported association between parabens and breast cancer is closely related to their theoretical estrogenic effects. The conversation regarding parabens and breast cancer has been fueled by the identification of parabens in human breast tumors and their presence in concentrations similar to what is needed to stimulate in vitro breast cancer cells.² The existing data do not confirm causation. An association with parabens in topical axillary personal care products has been theorized but not confirmed; for example, it was shown that paraben levels were highest in the axillary region of breast cancer tissue, including women who had never used deodorant. It was concluded that the presence of axillary parabens was due to sources other than topical axillary personal care products.¹³ Another study confirmed there was not an increased risk for breast cancer in patients who applied personal care products to the axillary area within an hour of shaving.¹⁴

The existing data do not support topical paraben exposure as a risk for breast cancer.

Final Thoughts

Parabens are preservatives frequently found in personal care products and exhibit a very low rate of associated ACD. Consumers may be exposed to parabens through foods, cosmetics, and medications. Although there have been consumer concerns regarding endocrine disruption or carcinogenicity associated with parabens, definite evidence of their harm is lacking in the scientific literature, and many studies confirm their safety.² With their high prevalence in personal care products and low rates of associated contact allergy, parabens remain ideal preservative agents.

Ultimately, contact dermatitis is a common yet often underrecognized dermatologic condition. To address this knowledge gap in clinical practice, we are proud to launch Final Interpretation, a new column in *Cutis* covering emerging trends in contact dermatitis. We will address pearls, pitfalls, and updates in contact dermatitis. Although our primary focus will be ACD, other important causes of contact dermatitis will be highlighted. Look for the inaugural column in the June 2019 issue of *Cutis*.

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