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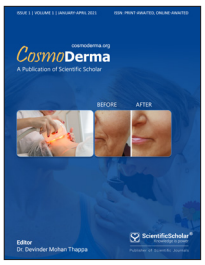

*Review Article*

# Understanding parabens – A literature review

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## ABSTRACT

Parabens are esters of p-hydroxybenzoic acid that are widely used in cosmetic, pharmaceutical, and industrial products, among other excipients, for their preservative and antimicrobial properties. However, since the late 1900s, parabens' use and safety have been surrounded by controversies relating to the potential causes of endocrine disruption, infertility, allergic skin reactions, and various cancers. Despite parabens being under a cloud of suspicion, these compounds have succeeded in extensive skin testing conducted by a variety of organizations in the United States. By dispelling misconceptions about the Paraben Paradox Theory, our review is aimed at determining the safety of topically applied parabens in cosmetics, the availability of alternatives, and their side effects.

**Keywords:** Parabens, Cosmetics, Paraben toxicity, Parabenoia, Paraben paradox

## INTRODUCTION

Over the past decades, due to widespread "parabenophobia" in society brought on by paraben toxicity rumors, consumers are choosing paraben-free items. On the other hand, the pharmaceutical, cosmetic, and food industries have extensively included parabens in formulating their products due to their preservative and antimicrobial activities.[1] The p-hydroxybenzoic acid (pHBA) aliphatic esters known as parabens are frequently employed as preservatives in the cosmetics, drugs, and food industries. They are white, odorless, tasteless, and exhibit neutral pH and solubility in water to achieve their preservative property.[2]

Ever since its incorporation into cosmetic use, numerous scientific studies have reported its link with endocrine disruption that may promote the development of male infertility and breast cancer**,** including allergic contact dermatitis (ACD) and childhood obesity. Paraben safety has been challenged due to its poor estrogenic properties *in vitro* and *in vivo*.[3] However, replacing paraben with less-researched alternative biocides may be risky and can have several negative effects.[4] The effects of paraben-containing topical products, the pros and cons of paraben use, debunking myths that revolve around the Paraben Paradox Theory, and identifying the available alternatives are the primary focus of our investigation.

## MATERIALS AND METHODS

The preliminary literature search was conducted on PubMed and Google Scholar using keywords such as "PARABENS," "PARABEN TOXICITY," "ALLERGIC CONTACT DERMATITIS,"

"PARABENOIA," "COSMETICS," "SAFETY," and "HEALTH RISK." A total of 33 articles were retrieved dated from 2015 to 2022. Articles included case reports, case series, systemic reviews, and retrospective and prospective studies. The references in each of the articles chosen from the preliminary search were also reviewed to identify any articles that highlighted and provided a deeper insight into the topic.

### Inclusion criteria

The present article was based on a comprehensive literature review. All the studies were performed in the last five years. The use of parabens was judged only on their topical application.

## RESULTS

The demand for parabens is increasing due to the expectation of long shelf life and microorganism-free cosmetic products.[5] Researchers have experimented with chemicals such as phenols and phthalates that can be combined with parabens. The term "endocrine disrupting chemicals" (EDCs) was developed since it is widely known that these phenols and phthalates interact with the thyroid, glucocorticoid, and androgen receptors to alter endocrine function,[6,7] causing adverse effects such as atopic dermatitis,[8] ACD,[9] pruritus and eczema,[10] and asthma-related outcomes in children. It should also be noted that most scientific investigations that identify parabens as EDCs involve oral exposure**,** whereas topical contact is less common.

Each experimental study carries a unique chance of bias. A comprehensive compilation of all the reviewed papers, along with their findings, is succinctly summarized in Table 1. The patients selected might have ingested these EDCs orally, resulting in an accumulation in breast tissue. Furthermore, neither the type of breast tumor nor the medical history of the patients were known. In addition, the sample size is a crucial factor in every experiment that aims to attain statistical power.[11]

Several strategies have been put forth to replace parabens, but each would need to undergo extensive safety and toxicity testing. Furthermore, when compared to estradiol, they have an estrogen receptor affinity that ranges from 2.5 million to 10,000 times lower.[11]

Careless replacement of parabens from consumer products with less researched, potentially hazardous substitutes can have major negative effects and pose a risk to human health.[11] Short parabens are most typically employed in cosmetic items, which limits their ability to block 17β-hydroxysteroid dehydrogenase (17β –HSD) (the enzyme that activates estrogen, 17β-HSD).[7] In addition, just 0.9% of the propylparaben that had been applied topically to the entire human body could be found in the urine in a free form**,**[4] indicating that parabens used in cosmetic items have no impact on health problems.

## DISCUSSION

Parabens are homologous esters of pHBA that were first commercialized in the 1930s due to their reported minimal toxicity, affordable manufacturing costs, and inert chemical properties. Parabens are aliphatic esters of pHBA widely used as preservatives in cosmetics, pharmaceuticals, and the food industry. In cosmetics, they are mostly found in topical preparations. The most common forms of paraben esters are methylparaben (MP), ethylparaben (EP), propylparaben (PP), and butlyparaben (BP). Whereas, isopropylparaben, isobutyl paraben, phenylparaben, and benzylparaben are infrequently used.[9] The Contact Allergen Management Program reported that 39.3% of cosmetics products, 34% of moisturizers, 11.5% of soaps, and 19% of sunscreens contain parabens.[11]

### Properties

An understanding of the pharmacokinetic, pharmacodynamic, and physicochemical properties of topical parabens is essential to analyze paraben-mediated effects in dermatology. Parabens have been actively added to topically applied cosmetics due to their preservative properties, minimal cytotoxicity or carcinogenicity, low cost, chemical inertness, and biodegradable nature. The preservative activity of parabens is acquired by their adequate water solubility. Their antimicrobial activity is related to mitochondrial failure dependent on inducing membrane permeability transitions followed by depolarization of mitochondria and ATP depletion. Inhibition of DNA and RNA synthesis may contribute to their antimicrobial properties. They also disrupt the bacterial lipid bilayer, hence interfering with membrane transportation and causing leakage of intracellular constituents.[2] The pharmacokinetic properties of parabens include absorption through the gastrointestinal tract and percutaneously, followed by hydrolysis to pHBA by keratinocyte carboxylesterases.[7] They are conjugated and rapidly excreted through urine.[2]

### The paraben paradox theory

A paradox is a purportedly conflicting claim that may or may not be true. To establish the pros and cons of paraben use, it is important to understand the Paraben Paradox Theory. Fisher, the first to use the phrase "paraben-paradox**,**" described two paradoxical effects of parabens. He stated that paraben-containing toiletries often produce false-negative results when patch-tested on the back. Furthermore, people with positive patch tests can continue using paraben-containing cosmetics without developing dermatitis**,** yet the

same groups reacted poorly when these topically applied treatments were administered on compromised skin. The esterase and microbial metabolite hypothesis proposed by Cashman and Warshaw, in 2005, further explained Fisher's theory of the paraben paradox. According to him, long-chain parabens like BP are the least reactive and are hydrolyzed through esterase in the subcutaneous tissue**,** whereas short-chain parabens (MP and PP) are the most reactive and are hydrolyzed in keratinocytes. Due to keratinocytes' poor metabolism, a damaged epithelium can allow short-chain parabens to penetrate it. This could explain the role of parabens in causing allergic dermatitis. The microbial metabolite hypothesis postulates that frequent usage of items containing parabens results in developing bacteria resistant to parabens. Due to these organisms, parabens hydrolyze into pHBA, which could worsen sensitivity.[2,6]

**Non-allergen of the year 2019**

Despite being a common preservative, parabens have been reported to be associated with endocrine disruption, breast cancer, infertility, obesity, and allergic skin reactions.[12] On the contrary, the American Contact Dermatitis Society (ACDS) declared parabens the non-allergen of the year 2019.[2,12] Furthermore, the North American Contact Dermatitis Group observed a low patch test reaction rate (0.6%) when a 12% concentration mix was patch-tested. The extremely low prevalence of ACD associated with parabens is one of the key reasons why they were named the ACDS non-allergen of the year.[11]

These contrasting reports of associated risks and the low occurrence of allergic reactions have led to widespread skepticism regarding paraben use. Hence, a detailed evaluation of cases reporting paraben toxicity is necessary.

**Parabens in wound dressing**

Parabens have been widely used as preservatives in topical wound care products for treating both minor and major wounds due to their shelf-life prolonging and anti-microbial properties. Torfs and Brackman reported that the role of paraben esters in skin sensitization and allergic dermatitis is uncommon due to their low prevalence rate.[13] Therefore, the use of paraben-containing products on wounded skin is regarded as safe provided they are added in non-toxic concentrations.

**Parabens and atopic dermatitis**

Atopic dermatitis, eczema, and allergies have been closely linked for many years. A study was conducted on Japanese children aged 0–3 years to examine the link between exposure to parabens and early-onset atopic dermatitis. Children with greater urine paraben concentrations than those with lower values had a considerably increased frequency of atopic dermatitis. Therefore, it was proven that exposure to parabens leads to atopic dermatitis.[8]

Another study reported that daily use of moisturizers causes allergic reactions in people with sensitive skin. On testing the products, it was found that they contained vitamins, oils, parabens, and other chemicals that could have aided in the elicitation of an allergic reaction, suggesting that parabens solely cannot cause allergic reactions, but they can act as instigators.[14]

**Association with breast cancer**

When parabens bind to estrogen receptors, they mimic the effects of natural estrogen and become EDCs with the potential to interfere with the action of endogenous hormones.[12,15] Their exposure in women has been connected with poor reproductive health, early development of breasts, pubic hair, and menarche.[15] A study investigating the relationship between prediagnostic urinary parabens and breast cancer in post-menopausal women diagnosed with breast cancer revealed a weak contrary risk association with total paraben exposure. The results of this study are in contradiction with the Long Island Breast Cancer Study Project's study**,** which established that increasing exposure to total parabens increased breast cancer risk, which was prominent in those with a normal body mass index (BMI). Hence**,** it is challenging to compare the above-listed findings since the former results were based on pre-diagnostic samples, whereas the latter was based on post-diagnostic samples.[16]

**Role in prostate cancer**

Recent research indicates that there is a substantial correlation between higher levels of parabens found in prostate cancer in patients' urine samples and an increase in the disease's severity, indicating that parabens may contribute to the development of prostate cancer.[17]

**Parabens as endocrine disruptors**

Parabens modulate endocrine functioning on various levels by binding to receptors as ligands. They impact estrogen, androgen, mineralocorticoid, progesterone, glucocorticoid, and thyroid receptors. Furthermore, they also disrupt the biosynthesis and biotransformation of natural hormones.[6]

Many studies have confirmed that parabens have led to disturbances in the concentrations of female steroid sex hormones. Increased levels of BP and decreased ratios of estradiol to progesterone are correlated. In males, they cause disturbances in testosterone levels due to differences in the lengths of their alkyl chains, interfering with steroidogenesis.

It was noted that butyl parabens did not affect the weight of the adrenal glands, whereas, in another study, it was also found that MP, EP, and PP increased the weight of the adrenal glands. However, some of the effects were only observed in animal models and never concurred within human studies. Consequently, further investigations are required, especially on the subject of endocrinology.[6]

**Effect of parabens on fertility**

Being EDCs, parabens can also adversely affect human reproduction. In females, significant associations were found between higher female urinary concentrations of MP and EP in urine and couple fecundity. The urinary concentration of MP and EP in females was associated with a 37% and 33% reduction in couple fecundity, given that females use more personal care products than men. In males, relatively low urinary concentrations of parabens were measured, which explained the lack of association between male fecundity. Hence, in the case of couple fecundity, females have been affected drastically more than men.[18]

**Parabens and respiratory disorders**

A cross-sectional study examined the association between urinary paraben concentrations, asthma attacks, and ED visits among children with asthma and with a current asthma diagnosis among all children (mean age 13.0 years). The association by sex was also evaluated. Exposure to both MP and PP was linked with increased prevalence odds of reporting ED visits in the prior 12 months among boys with asthma, despite boys having lower urinary paraben biomarker concentration**s**. This implies that MP and PP may contribute to symptom progression among those with asthma but may not directly contribute to the risk of developing asthma. The greater prevalence in males is thought to be linked to the fact that male subjects in general are more liable to have allergic diseases. Yet, no correlation with asthma was identified among children in the general population. However, a positive trend with PP and the current asthma diagnosis was noted. No significant interrelation between paraben use, prevalence, or morbidity of asthma was observed.[19]

**Childhood obesity patterns**

Although unlikely, paraben use has been linked to disrupted childhood obesity patterns when used by gestating mothers. From our literature search and analysis, several significant patterns of childhood obesity were identified, and we elaborate on them below. A study was conducted using generalized estimating equation analysis on BMI data to investigate the impact of prenatal paraben exposure on the weight development of children. No evidence of the association between parabens other than BP and childhood obesity was found. This effect seemed to have a stronger trend in girls compared to boys. Moreover, it was found that high exposure to parabens did not affect the risk for macrosomia at birth, but there was evidence for long-chain parabens to increase the risk for overweight children in early to mid-childhood.[20] Therefore, maternal exposure to BP may contribute to the progression of childhood obesity.

**Effect of age and ethnicity on paraben toxicity**

Age and ethnicity seem to have an impact on the different ways parabens have affected humans. According to reports, non-Hispanic black children are more likely to have current asthma.[21] MP exposure has also been reported to increase the risk of itchy rash in African Americans.[10]

**Current safety regulations and guidelines**

Various guidelines and recommendations have come forth to use parabens safely and to lessen their harm. The European Union allows the use of MP and EP as preservatives in cosmetics at maximum concentrations of 0.4% for one ester and 0.8% when used together. PP and BP are considered safe as preservatives in cosmetic products as long as the sum of their concentrations does not exceed 0.14%.

On the other hand, Asian regulations have prohibited the use of all parabens as preservatives in cosmetics, except EP, MP, and BP. The other guidelines are *in lieu* of the European ones. Canada has not specifically banned or restricted any parabens but has specified that their data about hormonal and oncogenic potential is lacking. For all the other recommendations, they have been in step with the FDA.

Three Asian studies have reported that the extensive use of parabens in cosmetics and the high concentrations in these products account for the higher rate of reactivity.[2] Hence, the attention of the cosmetics industry has been drawn toward finding natural and safer preservatives of plant origins to minimize the use of harmful substances.[21]

The existing toxicity experiments, which cover a variety of exposure pathways, show a low order of parabens' toxicity at concentrations that would be used in cosmetics, according to the Cosmetic Ingredient Review (CIR) Expert Panel's review.

CIR Expert Panel evaluated infant exposure separately from adult exposure to establish margins of safety (MOS). The safety margins (MOS) for infants varied from around 6000 for products with a single paraben to about 3000 for those with multiple parabens. For adults, the MOS ranged from 1690 for single paraben products to 840 for multiple paraben products.

The Expert Panel's opinion, which supports the safety of cosmetic goods containing paraben preservatives, is that these MOS most likely exaggerate the likelihood of any

**Table 1:** Risk of paraben exposure in reviewed articles.

| Title | Authors and year | Findings |
|---|---|---|
| Moisturizer allergy | Zirwas and Stechschulte (2008)[14] | • Despite extensive use of parabens, the incidence of allergy to them is lower than many other preservatives.<br>• Paraben can be a potential allergen but they have no't tested if they actually have an allergic reaction. They only test how much percentage of moisturizers contain allergens. |
| Interference of paraben compounds with estrogen metabolism by inhibition of 17β- HSDs | Engeli *et al.* (2017)[7] | • This work investigated the potential interference of parabens with the estrogen-activating enzyme 17β- HSD1 and the estrogen-inactivating 17β-HSD2. |
| Urinary concentrations of parabens and other antimicrobial chemicals and their Association with couples' fecundity | Smarr *et al.* (2017)[18] | • Female but not male partners' preconception urinary concentration of MP and EP were associated with a 37% and 33% reduction in couple fecundity as measured by a longer time to pregnancy. |
| Paraben exposures and asthma-related outcomes among children from the US general population | Quirós-Alcalá *et al.* (2019)[19] | • Interactions between paraben exposure and sex on current asthma diagnosis were not statistically significant |
| Parabens and their effects on the endocrine system | Nowak *et al.* (2018)[6] | • They modulate the functioning on different levels by binding onto receptor ligands.<br>• They disrupt the biosynthesis and biotransformation of natural hormones.<br>• In males they cause disturbances in testosterone levels due to variation in alkyl chain lengths which interfere in steroidogenesis<br>• In females, parabens were found to be higher in urinary concentration compared to males. |
| Maternal paraben exposure triggers childhood overweight development | Leppert *et al.* (2020)[20] | • Maternal exposure to BuP may trigger overweight development in early childhood.<br>• This effect seems to be stronger in girls compared to boys. |
| Methyl paraben may increase risk of pruritus in African Americans whereas triclosan is inversely associated with Pruritus and Eczema | Kim *et al.* (2019)[10] | • Methyl paraben exposure may increase the risk of itchy rash in African Americans. |
| Increased Prevalence of Atopic Dermatitis in Children Aged 0–3 Years Highly Exposed to Parabens. | Arafune *et al.* (2021)[8] | • There was an increased prevalence of atopic dermatitis in children aged 0–3 years and suggests it probably due to exposure to parabens in their early lives that may have resulted in the early onset of atopic dermatitis.<br>• Regarding the pathogenesis of the early onset of atopic dermatitis, the predominance of Th2 accompanying exposure to parabens is considered to lead to the onset of atopic dermatitis.<br>• The present results showed no significant differences in the involvement of atopic dermatitis and paraben exposure between sexes. |
| Risk of breast cancer and prediagnostic urinary excretion of bisphenol A, triclosan and parabens: The Multiethnic Cohort Study | Wu *et al.* (2021)[16] | • Breast cancer risk in a multiethnic population was unrelated to bisphenol A (BPA) and was weakly inversely associated with triclosan and paraben exposures. |
| Toxic Effects of Paraben and its Relevance in Cosmetics: A Review | Alaba, *et al.* (2022)[12] | • Parabens - not safe, has endocrine effects, breast cancer risks, allergies<br>• Although a report purportedly linking parabens in underarm cosmetics to breast cancer sparked widespread interest, a closer examination revealed no evidence of demonstrable risk;<br>• Obtained results may be unreliable for comparison on humans. |
| Environmental phenol and paraben exposure risks and their potential influence on the gene expression involved in the prognosis of prostate cancer | Alwadi *et al.* (2022)[17] | • Significant association of higher levels of EPs and PBs monitored in the urine samples of the US men with reported prostate cancer cases was observed.<br>• Higher levels of EP and PB in the urine samples are consistent with the increase in the severity, especially in the older population of 65 years and older, with higher BMI and high lipid concentrations in the blood.<br>• Hub genes, BUB1B, TOP2A, UBE2C, RRM2, and CENPF, shed light on the underlying molecular mechanisms triggered by EP and PB exposures and the hub genes potentially accommodate exposures of risk factors, including metabolic, comorbidity, age, or lifestyle, to exacerbate the severity of the disease. |

17β-HSD: 17β-hydroxysteroid dehydrogenase, BuP: Butyl Paraben, PP: Propylparaben, MP: Methylparaben, EP: Ethylparaben, BP: Butlyparaben, BMI: Body mass index, PB: Paraben

negative consequences (such as lower concentrations in usage or reduced penetration).[22]

## CONCLUSION

Based on the limited data available regarding parabens in cosmetics, we have found that the use of only parabens necessarily does not pose a threat to human health. Studies that experimented on animals using high doses of parabens could not be used to generalize findings to the human population.

Despite some uncertainties and the absence of complete scientific information, this should not prevent us from taking precautions. We advise adhering to the existing guidelines for paraben use in cosmetics, which call for concentrations of 0.4% for single use and 0.8% for paraben combinations.[2,7]

Nonetheless, a large majority of the population uses cosmetics excessively, which, in turn, causes the exposure to be far greater than the safer quantity, which leads to the development of unfavorable health outcomes.[21] Consumers should make conscious decisions when using cosmetics containing parabens in them.

### Ethical approval

The Institutional Review Board approval is not required.

### Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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### Conflicts of interest

There are no conflicts of interest.

### Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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