

# Parabens: The Importance and Safety of Preservatives

## WHAT ARE PARABENS? LET'S CLEAR IT UP.

Much like “gluten-free” for the food industry, “paraben-free” claims have been trendy in cosmetics for several years, however few consumers know what parabens are, let alone why they are avoiding them. Parabens are a family of preservatives derived from benzoic acid, which are used to protect both food and personal care products from microbial growth.



## SHOULD PRESERVATIVES BE AVOIDED?

Preservatives are an important component of any aqueous formulation as they help protect the end user from opportunistic pathogens such as bacteria, yeast and mold. It can be challenging to select preservatives that are simultaneously effective in eliminating or preventing the growth of bacteria or fungal cells but also not toxic to human cells. The ideal preservatives are effective against a wide range of microbes at a concentration that would be innocuous to people.<sup>1</sup>

In both the personal care and pharmaceutical industries, there is a trend towards marketing preservative-free or naturally preserved products in response to consumer perception.

Unfortunately, many “natural” or preservative-free products leave the product and ultimately the consumer unprotected from the full spectrum of potential microbial contamination.<sup>2,3,4</sup>

## Are you FULLY PROTECTED?



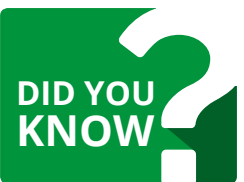
A well established way to determine the effectiveness of a preservative system is to challenge the formula by intentionally inoculating the product with a standard example of each microbe.<sup>1</sup> This microbial challenge will help to determine whether the product can withstand typical use and exposure to common environmental pathogens without fostering their proliferation. As patient safety is always of utmost concern throughout the development process, all of MEDISCA's aqueous bases must pass the USP <51> challenge test for preservative efficacy.

## WHY PARABENS?

At a very low concentration (less than 1%), parabens offer protection against a wide range of microbes.<sup>5</sup> For decades, they have been used as preservatives in food, drug and cosmetic products and are widely considered safe by regulatory bodies when used within specified concentrations (see **“What does the world think about parabens?”** for more details).

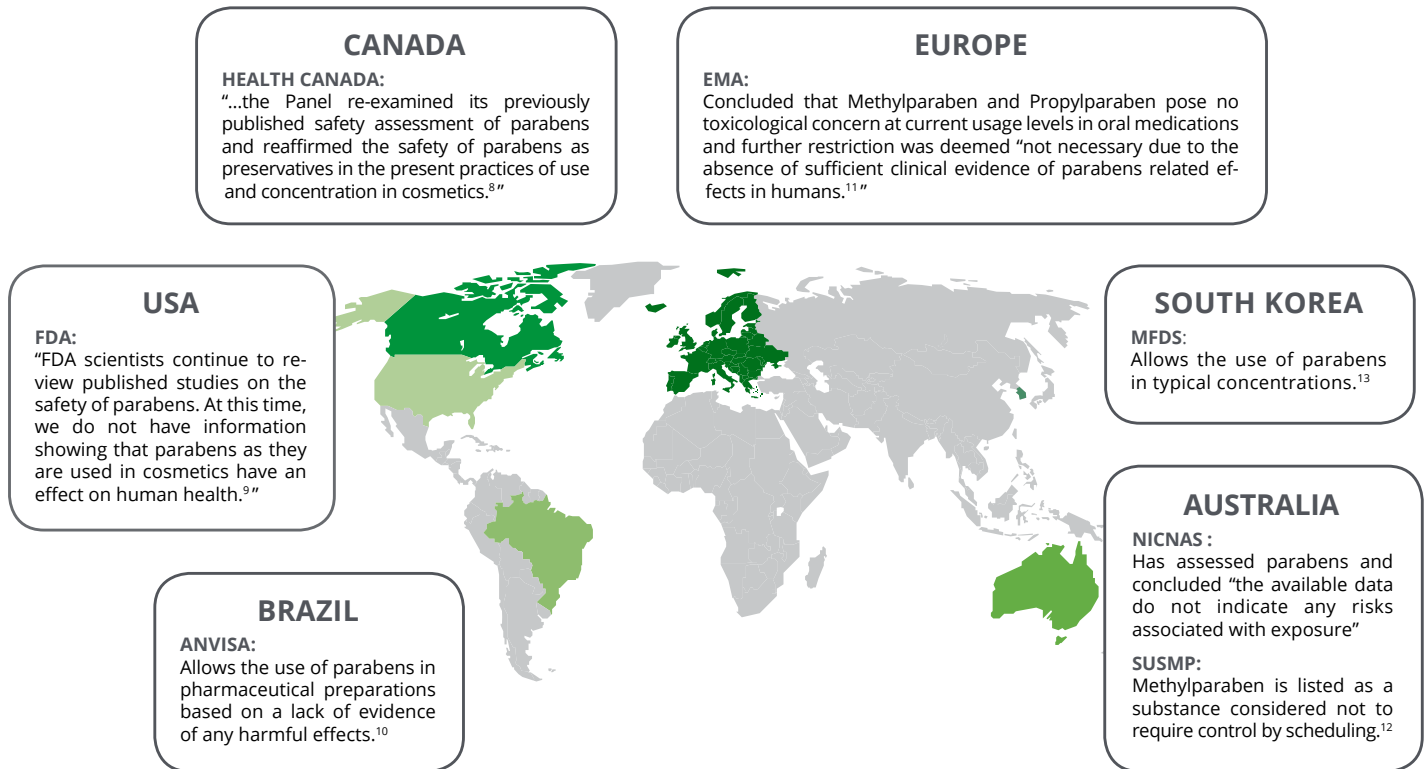
Parabens are quickly eliminated by the liver when consumed orally and are present in low levels in human tissues, indicating low bioaccumulation.<sup>6</sup> Although concerns have been raised regarding the potential for parabens to mimic estrogen in the body, their activity has been found to be lower even than that of phytoestrogens found in plants, and orders of magnitude lower than natural hormones in the body.<sup>7</sup>

Subsequent research has not justified the avoidance of parabens, especially in oral products which are processed by the liver, however one might choose to be extra cautious and avoid parabens specifically in topical products, as these bypass the liver. Fortunately, as topical products are not being ingested, there are more alternative preservatives to choose from to safely preserve topical products.<sup>1</sup> In oral products, parabens are one of the few adequately safe and effective options available to ensure sufficient microbial inhibition. They are also an ideal choice to satisfy healthcare providers' practical considerations by allowing for a multiple year shelf life at room temperature.<sup>1</sup>



Naturally occurring parabens can be found in trace amounts in fruits and vegetables such as blueberries and carrots<sup>8</sup>.

## WHAT DOES THE WORLD THINK ABOUT PARABENS?



## PARABENS CONCLUSIONS: LET'S SUM IT UP.

- ✓ Aqueous pharmaceutical products provide an ideal environment for microorganisms to grow. To this day, parabens remain an optimal preservative system in terms of safety and efficacy to prevent the risk for microbial contamination in oral products.
- ✓ The type and concentrations of parabens used by MEDISCA are well within the current trends in legislation.
- ✓ Parabens have been used in cosmetics, food and pharmaceutical products for decades and their use is permitted under the legal restrictions on health and cosmetics in North America, Brazil, Australia and the European Union.
- ✓ Studies published on parabens have repeatedly demonstrated their safety and efficacy with no causal link to any adverse health effects.<sup>14</sup>

## REFERENCES

1. David P. Elder, Ph.D, Patrick J. Crowley (2012): Antimicrobial Preservatives Part One: Choosing a Preservative System.
2. Molina-Cabrillana, J., Bolaños-Rivero, M., Alvarez-León, E., Sánchez, A., Sánchez-Palacios, M., Alvarez, D., & Sáez-Nieto, J. (2006). Intrinsically Contaminated Alcohol-Free Mouthwash Implicated in a Nosocomial Outbreak of Burkholderia cepacia Colonization and Infection. Infection Control & Hospital Epidemiology, 27(11), 1281-1282. doi:10.1017/S0195941700075147.
3. <https://www.productsafety.gov.au/news/cosmetics-recalled-after-failing-acc-testing>.
4. Ghulam, A. Keen, K. Tuleu, C. Wong, ICK. Long, P. (2007). Poor Preservation Efficacy Versus Quality and Safety of Pediatric Extemporaneous Liquids. Annals of Pharmacotherapy.
5. Rowe, Raymond C; Sheskey, Paul J; Quinn, Marian E (2009) Handbook of Pharmaceutical Excipients, 6th edition Pharmaceutical Press; American Pharmacists Association .
6. Abbas S1, Greige-Gerges H, Karam N, Piet MH, Netter P, Magdalou J.(2010) Drug Metab Pharmacokinet. 2010;25(6):568-77. Epub 2010 Oct 1.
7. Robert Golden, Jay Gandy, Guenter Vollmer (2005) A review of the endocrine activity of parabens and implications for potential risks to human health. Crit Rev Toxicol. 2005 Jun; 35(5): 435-458.
8. Health Canada, (2012) Consumer Product Safety: parabens.
9. US Food and Drug Administration (2016) parabens in Cosmetics.
10. ANVISA Resolução da Diretoria Colegiada - RDC nº 29 de 02/06/2012.
11. European Scientific Committee on Consumer Safety (2011). Opinion on parabens. European Commission.
12. NICNAS (2016): Human Health Tier II Assessment: parabens.
13. Korea Ministry of Food and Drug Safety Cosmetics Act; (2008) Notification No. 2008-57 on designation of cosmetics ingredients.
14. Witorsch, R. J., & Thomas, J. A. (2010). Personal care products and endocrine disruption: a critical review of the literature. Critical reviews in toxicology, 40(sup3), 1-30.