




PARABENS

– EVERYDAY ENDOCRINE DISRUPTERS

TO BE PHASED OUT



Parabens are extensively used as preservatives in cosmetics and personal care products. However this widespread use is of concern since parabens are not safe to use. They are endocrine disrupting chemicals, meaning that they can mimic hormones and adversely affect human health, for example the reproductive system.

The four most commonly used parabens are propyl-, butyl-, methyl- and ethylparaben, where current science suggests the first two to be the more hazardous. The four parabens are characterised as category 1 endocrine disrupters in the European Commission's database of potential endocrine disrupters.

Consumer awareness of health concerns related to parabens has increased during recent years. Parabens are still commonly used, but the market has started to shift away from them. To replace parabens, either less hazardous preservatives can be used, or changes in production and packaging can eliminate the need for preservatives. Sterisol, Weleda, Allison and pure shop are examples of companies producing paraben-free products.

ChemSec urges companies to speed-up the phase-out of parabens, consumers to ask for alternatives and EU policy-makers to act on the current scientific knowledge and regulate the use of these substances.

WHAT ARE PARABENS?

Parabens are a group of chemicals used as preservatives because of their antimicrobial properties. Over recent decades parabens have been extensively used in cosmetics and personal care products such as shampoos, deodorants and body lotions. They have been a cheap and efficient solution, functioning for almost any formulation. Previously parabens were regarded as safe compared to other preservatives, however that has changed.

Chemically speaking, parabens are the various esters of 4-hydroxybenzoic acid. The suffix “paraben” is used for declaration on cosmetics and personal care products. Four parabens are more frequently used: methylparaben and ethylparaben which can be referred to as “short-chained” parabens (referring to their chemical structure and the number of carbon atoms). Propylparaben and butylparaben are referred to as “long-chained” (on the same basis). There are also even longer chained parabens (pentyl-, heptyl-, octyl-) and branched-chained parabens (isopropyl-, isobutyl-, benzyl-, phenyl-), but these are not as commonly used and have not been as widely studied. Some forms of parabens are also used for the preservation of food and household chemicals. When methylparaben or ethylparaben are used in food they are declared as E218 and E214.

WHY IS THERE CONCERN OVER PARABENS?

There is an increasing number of scientific studies showing endocrine disruptive properties for parabens. Parabens can mimic the function of the female sex hormone oestrogen

and disturb the function of the male sex hormone androgen. Adverse effects observed in animals include malformation of reproductive organs in pups born by exposed females and decreased sperm production in exposed males. In most studies propyl- and butylparaben show more negative effects than methyl- and ethylparaben. All of these four parabens have been categorised as Category 1 endocrine disrupters in the European Commission’s database of potential endocrine disrupters. Category 1 lists substances for which there is evidence of endocrine disruption in animal studies (in vivo studies).

Parabens are so widely used today that measurable levels can be found in most people’s urine, blood or breast milk, for example. In two US studies propylparaben was found in more than 90 percent of the population. In a recent Norwegian study, the measured levels of parabens in frequent users of personal care products were higher than for any of the other environmental pollutants measured. Parabens are also spread in the aquatic environment, for example from swimmers using sunscreens, and from sewage treatment plants where they cannot always be removed from the incoming water. This vast exposure of the population and the environment causes concern, especially for individuals during sensitive stages of development, such as during foetal development, for young children and during puberty. As with other endocrine disruptive chemicals, effects may occur from low doses and may be delayed for years or decades after the exposure.

ACTION ON PARABENS

REGULATORY ACTIVITIES IN THE EU

The safety of parabens in cosmetics and personal care products has been discussed at political level in the EU in recent years. As stated above, the four most commonly used parabens have been identified as endocrine disrupters in the European Commission database of possible endocrine disrupters. However the EU Cosmetics Directive currently allows parabens as long as the paraben concentration does not exceed 0.4 percent for an individual paraben or 0.8 percent when used as a mixture.

In 2009 the Danish National Food Institute published a risk assessment for parabens, demonstrating a potential risk, especially for small children, with the current use of the long-chained parabens. In March 2011 Denmark banned the use of propyl- and butylparaben in products intended for children under three years of age.

The European Commission has several times asked its Scientific Committee on Consumer Products (SCCP) for its opinion on potential risks with the current use of parabens. Taken together, the opinion statements from December 2010 and October 2011 suggest that the use of methylparaben and ethylparaben is safe, but recommend that the levels of propyl- and butylparaben should be lowered to 0.19 percent. For products intended for the “nappy area” for children under six months of age, SCCP states that it is not possible to exclude the risk of using butyl- and propylparaben. For other parabens, SCCP has stated that there was not

enough data to make an assessment at the time. Currently (April 2013) there is a pending request from the European Commission for an updated opinion, this time with respect to new data on propyl- and butylparaben in all age groups including exposure from sunscreens for children under the age of three.

The EU Cosmetics Directive regulates parabens in cosmetics and personal care products with regard to human health concerns, and the EU chemicals regulation REACH does the same with regard to environmental concerns and for other product groups.



CONSUMER AWARENESS AND PRESSURE

Consumer awareness regarding health concerns over parabens has increased in recent years. Since the content of personal care and cosmetic products has to be clearly stated on packaging it is relatively easy for consumers to avoid products containing parabens and to ask for alternatives.

Environmental and consumer organisations recommend the avoidance of parabens, and a number of European and US consumer organisations have lately brought attention to endocrine disruptive chemicals in cosmetics and personal care products. Information for consumers can, for example, be found at

www.safecosmetics.org and www.goodguide.com.

The Danish and Norwegian Consumer Councils, together with the Swiss organisation Federation Romande des Consommateurs, have specifically addressed 17 chemicals present on the European Commission's database of potential endocrine disrupters that are allowed and used in personal care products. Methyl-, ethyl, propyl- and butylparaben are among these 17 chemicals. Activities have included campaigns encouraging consumers to report all products containing any of these substances, listing companies that have or have not phased them out, as well as a smartphone app for quick identification of products containing these endocrine disrupters.

PARABENS ON THE SIN LIST

The SIN List contains substances that ChemSec has identified as Substances of Very High Concern based on the criteria established by the EU chemical regulation, REACH.

In May 2011 ChemSec added propyl- and butylparaben to the SIN List 2.0 to highlight the importance of including them on the REACH candidate list of Substances of Very High Concern, due to their endocrine disruptive properties. The inclusion on the SIN List was made after a scientific literature review performed by the Endocrine Disrupting Exchange in the US, representing some of the world's leading scientists in the field. At the time there were not enough scientific studies to include methyl- and ethylparaben on the SIN List, however the available data suggests that these are also endocrine disruptive chemicals, and that they are similar to the long-chained parabens in both structure and properties. ChemSec therefore recommends an immediate phase-out of long-chained parabens and an intensified search for alternatives, as well as the phasing out of short-chained parabens.

SUBSTITUTES FOR PARABENS

WHY ARE PRESERVATIVES USED?

Preservatives are used to prevent the growth of microorganisms. Microbial contamination of personal care products is unwanted and could, in addition to spoiling the odour or appearance of the product, spread infections to the user. A major source of contamination of products is in fact the user, since bacteria and fungi are always present on the skin.

The amount and type of preservatives needed to prevent this depends on the type of product, the package and the shelf life of the product. According to the EU Cosmetics Directive a product should have a shelf life of at least 30 months and a period of safe use after opening should be stated on the packaging. The Cosmetics Directive also lists all preservatives that are allowed for use in cosmetics in Europe.

The need for preservation is also dependent on the product itself, for example the water activity and the pH decide how easily microorganisms can grow in the product. It may be necessary to preserve not only the final product, but also the raw materials used in production. The need for preservation is also dependent on the conditions during manufacturing. If the product is not contaminated during production, preservation only needs to cover the use phase.

It is possible to produce personal care products without preservatives – if these are produced under clean conditions and can be contained in packaging that allows no transfer of microorganisms from the user to the product.

HOW TO REPLACE PARABENS

There are two main approaches to eliminating parabens:

1. Changes in formulation, processes and packaging, so that no preservatives are needed
2. Chemical solutions, using other preservatives than parabens

There seems to be no universal substitute for parabens, and the best alternative will be dependent on the type of product. From a company perspective, it is favourable to avoid multiple substitutions and therefore to avoid substitutes with other hazardous properties, including formaldehyde and formaldehyde donors, such as imidazoline urea. Other unsuitable alternatives are triclosan and isothiazolinone compounds, sometimes called kathon.

It is difficult to find publically available information on the details of how companies have replaced parabens, as this often is confidential business information.

Replacing parabens might be a challenging task, but more and more companies produce products and brands free of parabens, showing that replacement of parabens is possible.

COMPANIES OFFERING PARABEN-FREE PRODUCTS

The Danish Consumer Council in March 2012 produced a list of brands available in Denmark that were free of the 17 endocrine disrupting chemicals previously mentioned, including parabens. Among these companies are Aloe Vera Group, Dr Hauschka, Cliniderm and Rudolf Care.

Sterisol, Weleda, Allison and pure shop are also companies that produce or sell paraben-free products. Read about their view on parabens and their paraben-free solutions below:

STERISOL HAS CHOSEN A FULLY PRESERVATIVE-FREE PACKAGING SOLUTION

Sterisol AB (www.sterisol.se) is a Swedish company producing skin care products mainly for professional use but lately also for consumers. The manufacturing facility is highly automated and operates under strict cleanroom conditions. Together with an air- and bacteria-tight packaging that does not allow any contamination from the user to the product, there is no need to use any preservatives in the products.

“Preservatives are among the most common causes of allergy development and we are therefore proud to be able to offer a wide range of personal care products without any preservatives inclusive parabens. This due to our unique packaging technique which protects the contents from any contamination also in use”

Björn Rylander, director at Sterisol

WELEDA NEVER USED PARABENS IN THE FIRST PLACE

Weleda (www.weleda.com) is an international company, founded in Switzerland in 1921. The company manufactures natural and organic cosmetics and pharmaceuticals for anthroposophic therapy.

“As a manufacturer of natural and organic cosmetics our fundamental position is not to use synthetic colour or perfume, silicon, paraffin and other petrol-based products, or any synthetic fats. Because of this, we have never considered using synthetic preservatives (such as parabens). The stability of our products is instead achieved by thorough composition of the formulas where the relation between oils, water and other ingredients is well balanced. Among the ingredients contributing to preservation are natural essential oils, alcohol and extracts from medical plants. Their optimised composition helps to ensure preservation. In addition, we avoid potential contamination during the use-phase by using well adapted primary packaging materials”

*Christian Witzig,
Head of Innovation Management at Weleda*

ALLISON HAS NOT USED PARABENS SINCE 2009

Allison (www.allison.dk) is a Danish cosmetics manufacturer with several brands.

“We stopped using butylparaben and isobutylparaben around 2005 and from 2009 we haven’t made new products containing parabens. Among the alternatives to parabens we use are sodium benzoate, dehydroacetic acid, benzoic acid and potassium sorbate”

Helle Petersen, sales and marketing assistant at Allison.

PURE SHOP DOES NOT SELL ANY PRODUCTS WITH PARABENS

pure shop in Copenhagen (www.pureshop.dk) is the largest organic skin care store in Europe, and its products are also available through an on-line shop. All products sold are checked against a list of unwanted ingredients, and parabens are among the ingredients not allowed in pure shop products.

“As the only organic beauty store we do not allow any of the following three problematic synthetic preservatives: parabens, phenoxyethanol and sodium hydroxymethylglycinate in any of our brands. All skin care products at pure shop are organic, plant-based products without synthetic or harmful ingredients and without substances suspected by the EU to be hormone disrupting”

pure shop states on their website.

WHAT NEEDS TO BE DONE

ChemSec recommends an immediate phase-out of long-chained parabens, as well as the phasing out and intensified search for alternatives to the short-chained parabens. More specifically, we recommend the following actions:

BUSINESS

- ☑ When developing new products: do so without parabens
- ☑ Increase the percentage of the product portfolio that is paraben-free
- ☑ Immediately phase out all long-chained parabens
- ☑ Start phasing out short-chained parabens

CONSUMERS

- ☑ Do not buy products containing parabens (look through the ingredient list on the packaging of cosmetic and personal care products)
- ☑ Ask for products without parabens

POLICY

A step-wise approach to reduce paraben exposure:

- ☑ Accept the Danish ban EU-wide, prohibiting propyl- and butylparaben in products intended for children under three years of age.
- ☑ Exclude all parabens from the list of allowed preservatives in the EU Cosmetics Directive for all age groups.
- ☑ Include propyl- and butylparaben on the REACH candidate list of Substances of Very High Concern to also target uses beyond cosmetics and with respect to effects seen in the environment.



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www.goodguide.com

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