

Public consultation on butyl and propylparabens

in the framework of Regulation (EC) no 1223/2009 of the European Parliament and of the Council on cosmetic products

1. Background

Parabens are regulated as preservatives in entry 12 of Annex V to [Regulation \(EC\) No 1223/2009](#) on cosmetic products under the denomination 4-hydroxybenzoic acid and its salts and esters, with a maximum concentration of 0.4 % for single ester and 0.8 % for mixtures of esters.

The SCCS adopted an opinion on parabens in December 2010¹, followed by a clarification of October 2011 in response to the Danish unilateral decision to ban propylparaben and butylparaben, the isoforms and their salts in cosmetic products for children under three years of age², taken in accordance with article 12 of Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. The conclusions of 2010 and 2011 were confirmed by the SCCS in an additional opinion of May 2013³.

The SCCS confirmed that methylparaben and ethylparaben are safe at the maximum authorized concentrations. In addition, the SCCS noted that limited to no information was submitted for the safety evaluation of isopropylparaben, isobutylparaben, and phenylparaben. Therefore, for these compounds, the human risk cannot be evaluated. The same is true for benzylparaben and pentylparaben. The Commission is in the process of banning these five compounds.

The SCCS considered the use of butylparaben and propylparaben as preservatives in finished cosmetic products as safe to the consumer, as long as the sum of their individual concentrations does not exceed 0.19% (as esters). These two substances are the subject of the current public consultation.

For general cosmetic products containing these two parabens, excluding specific products for the nappy area, the SCCS considered that there is no safety concern in children (any age group) as the Margin of Safety was based on very conservative assumptions, both with regards to toxicity and exposure. However, the SCCS maintained that in the case of children below the age of six months, and with respect to butyl and propylparabens present in leave-on cosmetic products designed for application on the nappy area, a risk cannot be excluded in the light of both the immature metabolism and the possibly damaged skin in this area. Based on a worst case assumption of exposure, safety concerns might be raised.

2. Action proposed by the Commission

The Commission envisages amending Annex V of the Cosmetics Regulation (EC) No. 1223/2009 to restrict the use of butylparaben and propylparaben as recommended by the SCCS.

¹ [SCCS/1348/10 Revision 22 March 2011.](#)

² [SCCS/1446/11.](#)

³ [SCCS/1514/13.](#)

However, for reasons of consistency with the current entry 12 of Annex V to Regulation (EC) No 1223/2009 on cosmetic products, the recommended maximum concentration of 0.19% as esters should be changed into its equivalent as acid (0.14%).

In addition, in light of the concerns raised by the SCCS regarding the use of parabens in leave-on cosmetic products designed for application on the nappy area of children under the age of six months, and for practical reasons linked to the fact that products for infants are usually marketed for children under three years, butylparaben and propylparaben should be prohibited in leave-on cosmetic products designed for application on the nappy area of children below three years.

Lastly, undertakings should be granted six months to place on the market compliant products, and twelve months to withdraw from the market non-compliant products after the entry into force of this Regulation.

The Commission will therefore propose that entry 12 of Annex V to Regulation (EC) No 1223/2009 is amended and entry 12a is added as follows:

	Substance Identification				Conditions			
Reference number	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	Wording of conditions of use and warnings
a	b	c	d	e	f	g	h	i
12	4-Hydroxybenzoic acid and its Methyl- and Ethyl-esters, and their salts	4-Hydroxybenzoic acid, methylparaben, potassium ethylparaben, potassium paraben, sodium methylparaben, sodium ethylparaben, ethylparaben, sodium paraben, potassium methylparaben, calcium paraben	99-96-7, 99-76-3, 36457-19-9, 16782-08-4, 5026-62-0, 35285-68-8, 120-47-8, 114-63-6, 26112-07-2, 69959-44-0	202-804-9, 202-785-7, 253-048-1, 240-830-2, 225-714-1, 252-487-6, 204-399-4, 204-051-1, 247-464-2, 274-235-4		0,4 % (as acid) for single ester 0,8 % (as acid) for mixtures of esters		
12a	Butyl 4-hydroxybenzoate	Butylparaben	94-26-8,	202-318-7,	Not to be used in	0,14% (as acid) for the		For leave-on

	<p>and its salts</p> <p>and</p> <p>Propyl 4-hydroxybenzoate and its salts</p>	<p>propylparaben</p> <p>sodium propylparaben</p> <p>sodium butylparaben</p> <p>potassium butylparaben</p> <p>potassium propylparaben</p>	<p>94-13-3,</p> <p>35285-69-9,</p> <p>36457-20-2,</p> <p>38566-94-8,</p> <p>84930-16-5</p>	<p>202-307-7,</p> <p>252-488-1,</p> <p>253-049-7,</p> <p>254-009-1,</p> <p>284-597-5</p>	<p>leave-on products intended to be used on the nappy area of children under three years of age.</p>	<p>sum of the individual concentrations of butyl- and propylparaben</p> <p>0,8% (as acid) for mixtures of esters mentioned in entry 12 and propyl and butylparabens, where the sum of the individual concentrations of butyl- and propylparaben does not exceed 0,14%</p>	<p>products intended to be used on children under three years of age:</p> <p>"Do not use on the nappy area"</p>
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3. Public consultation

DG Health & Consumers would like to invite any interested parties to submit their comments on the considered measure and on its possible impact.

With relation to the economic impact the information/comments should refer, *inter alia*, to the following topics:

- competitiveness, markets and trade,
- direct and indirect costs imposed on business, including SMEs,
- innovation and research,
- specific regions, sectors or workers,
- third countries and international relations,
- macroeconomic environment.

4. Who can submit comments

Any interested parties, including:

- Authorities of the Member States,
- manufacturers of cosmetic products,
- producers of these substances,
- relevant industry and consumers associations

are welcome to submit their comments on the considered measure and on its possible impact.

5. How to submit your contribution

Any comments should be sent with the reference:

"Butyl and Propylparabens - Public Consultation"

by mail or e-mail by **1st November 2013** at the latest to:

European Commission
Directorate General Health and Consumers
Unit B/2, Health Technology and Cosmetics,
Office DM24 02/082
B-1049 Brussels,
Belgium

E-mail: sanco-cosmetics-and-medical-devices@ec.europa.eu

6. Languages

A summary of this public consultation is available in all EU languages at the following links:

[BG - Кратка информация](#)

[CZ - Stručné informace](#)

[DA - Kort orientering](#)

[DE – Informationsvermerk](#)

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