

# SAFEGUARDS

## CONSUMER GOODS AND RETAIL

COSMETICS, PERSONAL CARE AND HOUSEHOLD

NO. 182/14 OCTOBER 2014

## REGULATION 1004/2014/EU: EU RESTRICTS THE USE OF BUTYL & PROPYL PARABENS IN COSMETIC PRODUCTS

In order to ensure the safety of cosmetic products for human health, the European Commission has adopted REGULATION (EU) No 1004/2014 that restricts the use of butyl and propyl parabens in leave-on cosmetic products designed for application on the nappy area of children below the age of three years. This was published in the Official Journal on 18 September 2014 and amends Annexes V of existing Regulation (EC) No 1223/2009.

### Background

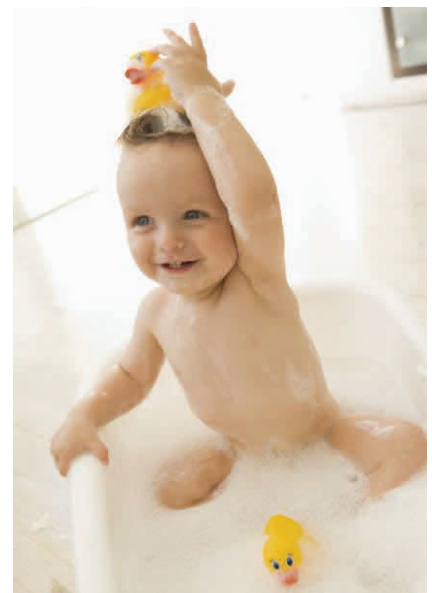
The Scientific Committee on Consumer Safety (SCCS) confirmed that concerning butylparaben and propylparaben present in leave-on cosmetic products designed for application on the nappy area of children below the age of six months, a risk could not be excluded in light of both the immature metabolism of such children and the possibility of damaged skin in the nappy area. Based on a worst case assumption of exposure, safety concerns might be raised.

The European Commission has overtaken (for practical reasons linked to the fact that products for infants are usually marketed for children under three years) and adopted the opinions from SCCS, and now it is incorporated into the EU Cosmetic Regulation EC 1223/2009 as an amendment as follows:

**ANNEX V (LIST OF PRESERVATIVES ALLOWED) IS AMENDED AND ENTRY 12 IS REPLACED BY THE FOLLOWING:**

### REFERENCE:

- [1 OPINION ON Parabens, SCCS/1348/10 Revision 22 March 2011, adopted on 14 December 2010](#)
- [2 COMMISSION REGULATION \(EU\) No 1004/2014 of 18<sup>th</sup> September 2014 amending Annexes II to V to Regulation \(EC\) No. 1223/2009 of the European Parliament and of the Council on cosmetic products](#)



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	<ul style="list-style-type: none"> <li>4 Hydroxybenzoic acid</li> <li>methylparaben</li> <li>potassium ethylparaben</li> <li>potassium paraben</li> <li>sodium methylparaben</li> <li>sodium ethylparaben</li> <li>ethylparaben</li> <li>sodium paraben</li> <li>potassium methylparaben</li> <li>calcium paraben</li> </ul>	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'		

**ENTRY 12A IS INSERTED:**

SUBSTANCE IDENTIFICATION					CONDITIONS			
Reference NO.	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
'12a	Butyl 4-hydroxybenzoate and its salts Propyl 4-hydroxybenzoate and its salts	<ul style="list-style-type: none"> <li>Butylparaben</li> <li>propylparaben</li> <li>sodium propylparaben</li> <li>sodium butylparaben</li> <li>potassium butylparaben</li> <li>potassium propylparaben</li> </ul>	94-26-8 94-13-3 35285-69-9 36457-20-2 38566-94-8 84930-16-5	202-318-7 202-307-7 252-488-1 253-049-7 254-009-1 284-597-5		0,14 % (as acid) for the sum of the individual concentrations 0,8 % (as acid) for mixtures of substances mentioned in entry 12 and 12a, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0,14 %	Not to be used in leave-on products designed for application on the nappy area of children under three years of age.	For leave-on products designed for children under three years of age: "Do not use on the nappy area"

## TIMELINE

This regulation entered into force on 16 October 2014.

From 16 April 2015 only cosmetic products which comply with this Regulation shall be placed on the Union market.

From 16 October 2015 only cosmetic products which comply with this Regulation shall be made available on the Union market

## SGS SOLUTION:

It is crucial for all cosmetic, personal care and household products to be safe, effective and stable. SGS provides testing, inspection, auditing and consulting services to manufacturers, distributors and importers to ensure a high level of product quality in every area. Our state of the art laboratories offer custom-made solutions for chemical, biophysical, microbiological, stability and biological aspects. We also have extensive capabilities in performance testing, claim support studies and consumer panels. Our testing is conducted according to customer specific or recognised standard methods, some of which were developed by SGS. Our cosmetic safety assessors and other technical experts can support customers by making sure new products comply with regulatory requirements.



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