

*Status: Point in time view as at 31/12/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 1004/2014, ANNEX. (See end of Document for details)*

ANNEX

Annex V to Regulation (EC) No 1223/2009 is amended as follows:

(1) entry 12 is replaced by the following:

Reference number	Substance Identification				Conditions			Wording of conditions of use and warnings
	Chemical name/ INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
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	99-06-7 99-06-3 36457-192-3 4782-082-2 5026-62-0 36285-682-8 120-47-8 114-63-6 26112-072-2 6059-442-4	202-804-9 202-785-7 203-048-1 240-830-2 025-714-1 282-487-6 204-399-4 204-051-1 227-464-2 204-235-4		0,4 % (as acid) for single ester 0,8 % (as acid) for mixtures of esters'		

(2) entry 12a is inserted:

Reference number	Substance Identification				Conditions			Wording of conditions of use and warnings
	Chemical name/ INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
'12a	Butyl 4-hydroxybenzoate and its salts	Butylparaben propylparaben sodium propylparaben sodium butylparaben	0426-8 0426-3 35285-692-3 36457-202-3 38566-942-4 8430-162-3	202-318-7 202-307-7 202-488-1 203-049-7 204-009-1 204-597-5		0,14 % (as acid) for the sum of the	Not to be used in leave-on products	For leave-on products designed for

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Propyl 4- hydroxy and its salts	potassium butylparaben potassium propylparaben			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 %	designed for application on the nappy area of children three years of age.	children under three years of age: “Do not use on the nappy area”
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