Commission Regulation (EU) 2016/622 of 21 April 2016 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/622

of 21 April 2016

amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products⁽¹⁾, and in particular Article 31(2) thereof,

Whereas:

- (1) On 27 March 2014, the Scientific Committee on Consumer Safety ('SCCS') issued a scientific opinion on potassium hydroxide⁽²⁾, which concluded that potassium hydroxide is safe for use as a callosity softener/remover up to a maximum concentration of 1,5 % w/w.
- (2) The SCCS also concluded that the safe use of cosmetic products containing free potassium hydroxide in concentrations from 0,5 % w/w depends on responsible risk management, through warnings and extensive guidance for use.
- (3) Following the scientific opinion of the SCCS, the Commission considers that potassium hydroxide should be considered safe for use as a callosity softener/remover up to a maximum use concentration of 1,5 % w/w.
- (4) In light of the conclusion of the SCCS regarding responsible risk management with respect to products containing free potassium hydroxide in concentrations from 0,5 % w/w, the Commission considers that cosmetic products containing potassium hydroxide for use as a callosity softener/remover should bear a warning referring to the directions for use.
- (5) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 April 2016.

For the Commission The President Jean-Claude JUNCKER

ANNEX

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

(1) entry 15a is replaced by the following entry:

Ref No.	Substa	Substance identification				Restrictions			Wording	
	ChemicaName CAS			EC		t Maxim	utother	of		
	name/	of	number	r numbei	· type,	concentration		conditio	ns	
	INN	Comme	on		body	in		of use		
		Ingredients			parts	ready		and		
		Glossar			T	for		warnings		
						use				
						prepara	ation			
a	b	c	d	e	f	g	h	i		
15a	Potassiu	mPotassiu	m1310-58-	3/115-118-17-	3-/2 15-18					
100	or	hydroxic	le/		(a)	(sià il	5	(a)	Contain	
	sodium	sodium				cuticle	⁰⁄₀ ^b		alkali	
		letydroxic	le			solvent		Avoid		
	Ilyuloxit	Jeryarozio						contact		
								with		
								eyes		
								Čan		
								cause		
								blindness	s	
								Кеер	,	
								out of		
								reach		
								of		
								children		
					a >	2 % ^b Hair	General	Contains		
					(b)		use	alkali		
						straighte	ner	Avoid		
								contact		
								with		
								eyes		
								Can		
								cause	_	
								blindness	5	
								Keep		
								out of		
								reach		
								of		
								children		
						4,5 % ^b	Professio) Frædr		
							use	professio	nal	
								use		
								only		
	other uses of p							Jilly		

b The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column g.';

			Avoid contact with eyes Can cause blindnes	55 -
	(c)	pH (adjuster for depilatorie	(c) (df) < 12,7 es Avoid contact with eyes	Keep out of reach of children
For other uses of potassium hydroxide see Anney	(d)	Other uses as pH adjuster	(d) pH < 11	_

a For other uses of potassium hydroxide, see Annex III, No 15d.

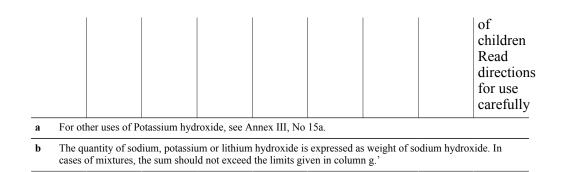
b The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column g.';

(2) entry 15d is inserted:

Ref No.	Substance identification				Restrict	Wording		
	Chemia name/ INN	Ingredi	Name CAS	EC r numbe	I	t Maximu@then concentration in ready for use preparation		
a	b	c	d	e	f	g	h	i
ʻ15d		nPotassiu Jerydroxic		- 3 215-181-	Callosity softener/ remover	1,5 % ^b		Contains alkali Avoid contact with eyes Keep out of reach

a For other uses of Potassium hydroxide, see Annex III, No 15a.

b The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column g.'



- (**1**) OJ L 342, 22.12.2009, p. 59.
- (2) SCCS/1527/14, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/

There are currently no known outstanding effects for the Commission Regulation (EU) 2016/622.