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		Substance identification				tions		Wording		
No.	Chemic name/	aName of	CAS	CAS EC number number		Product Maximutother type, concentration			of conditions	
	INN	of Commo Ingredi Glossar	on ents	r numbel	body parts	in ready for use prepara		of use and warnings		
a	b	c	d	e	f	g	h	i		
"15a	sodium	nPotassium 310 hydroxide/ sodium Jetydroxide		8-3/115-1108-17	3/2 15-18 (a)		5 %	(a) Avoid contact with eyes Can cause blindness Keep out of reach of children	Contain alkali s	
					(b)	2 % ^b Hair straighte	General Contai use alkali Avoid contac with eyes Can cause blindre Keep out of reach of childre		255	
						4,5 % ^b	Professio use	fat professio use only	nal	

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.';

			Avoi cont with eyes Can caus blind	act
	(c)	pH (adjuster for depilatori	(c)	of reach of children id act
For other uses of potassium hydroxide, see Annex 1	(d)	Other uses as pH adjuster	(d) pH < 11	

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

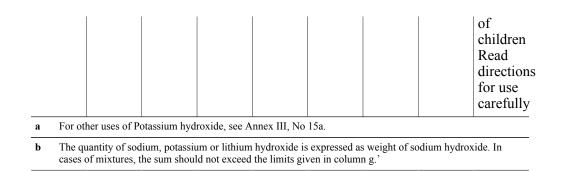
b The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column g.';

(2) entry 15d is inserted:

Ref No.	Substance identification				Restrict	Wording		
	Chemic name/ INN	caName of Commo Ingredi Glossar	on ents	EC r number		t Maximutother concentration in ready for use preparation		of condition of use and warning
a	b	c	d	e	f	g	h	i
ʻ15d		nPotassiu Idrydroxid		- 2 15-181-	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.