

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<sup>(1)</sup>, 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<sup>(2)</sup>, 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.

---

**Status:** Point in time view as at 31/12/2020.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) 2016/622. (See end of Document for details)

---

### *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

*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) 2016/622. (See end of Document for details)*

## ANNEX

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

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

Ref No.	Substance identification				Restrictions			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
15a	Potassium or sodium hydroxide	Potassium hydroxide/ sodium hydroxide	1310-58-2	113-107-3	3/215-185-5 (a)	Nail cuticle solvent	5 % <sup>b</sup>	(a) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children
					(b)	Hair straightener	2 % <sup>b</sup>	General use Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children
					4,5 % <sup>b</sup>	Professional use	Professional use only	

**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.;

*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) 2016/622. (See end of Document for details)*

								Avoid contact with eyes Can cause blindness	
					(c)	pH adjuster for depilatories	(c)	<del>(d)</del> pH < 12,7  Avoid contact with eyes	Keep out of reach of children
					(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				Restrictions			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
15d	Potassium hydroxide	Potassium hydroxide	1310-58-3	215-181-3	Callosity softener/remover	1,5 % <sup>b</sup>		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.;

---

*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) 2016/622. (See end of Document for details)*

---

								of children Read directions for use carefully
<b>a</b>	For other uses of Potassium hydroxide, see Annex III, No 15a.							
<b>b</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. <sup>7</sup>							

---

**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) 2016/622. (See end of Document for details)

---

(1) [OJ L 342, 22.12.2009, p. 59.](#)

(2) [SCCS/1527/14, sccs\\_o\\_154.pdf](#) [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/)

**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) 2016/622.