# 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.

**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

***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[a] | Potassium hydroxide/ sodium hydroxide | 1310-58-3/ 1310-73-2 | 215-181-3/ 215-185-5 | (a) cuticle solvent | (a) nail 5 %[b] | 5 | (a) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children |
| | | | | | (b) straightener | 2 %[b] Hair | General use | Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children |
| | | | | | | 4,5 %[b] | Professional use | For 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.’;