Commission Regulation (EU) 2016/1120 of 11 July 2016 amending Annex IV to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1120

of 11 July 2016

amending Annex IV 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) Carbon Black is authorized as a colorant in cosmetics under entry 126 of Annex IV to Regulation (EC) No 1223/2009. The Scientific Committee on Consumer Safety ('SCCS') carried out a risk assessment of Carbon Black (nano) and adopted an opinion on 12 December 2013[(2)], in which it concluded that the use of Carbon Black in its nano-structured form (with a primary particle size of 20 nm or larger) at a concentration up to 10 % w/w as a colorant in cosmetic products does not pose any risk of adverse effects in humans after application on healthy, intact skin.

(2) Moreover, the SCCS indicated, in a further opinion of 23 September 2014 for clarification of the meaning of the term 'sprayable applications/products' for the nano forms of Carbon Black CI 77266, Titanium Dioxide and Zinc Oxide[(3)], that the opinion on Carbon Black (nano) does not apply to applications that might lead to exposure of the consumer's lungs to Carbon Black nanoparticles by inhalation.

(3) The SCCS conclusions apply to Carbon Black (nano) with a defined purity and impurity profile. Furthermore, the purity criteria set out for non-nano Carbon Black are no longer up-to-date and should be removed, as Commission Directive 95/45/EC[(4)] was repealed by Directive 2008/128/EC[(5)]. Those criteria should be replaced by the criteria applicable to Carbon Black (nano).

(4) In light of the SCCS opinions mentioned above, the Commission considers that Carbon Black (nano) (according to the SCCS's specifications) should be authorized for use as a colorant in cosmetic products at a maximum concentration of 10 % w/w, except in applications that may lead to exposure of the end user's lungs by inhalation.

(5) The Commission considers that Annex IV to Regulation (EC) No 1223/2009 should be amended for the purpose of adapting it to technical and scientific progress.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1120. (See end of Document for details)*

(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 IV 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, 11 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1120. (See end of Document for details)*

ANNEX

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

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/ Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
‘126	Carbon black	77266	1333-86-4, 7440-44-0	215-609-9, 231-153-3, 931-328-0, 931-334-3	Black			Purity > 97 %, with the following impurity profile: Ash content ≤ 0,15 %, total sulphur ≤ 0,65 %, total PAH ≤ 500 ppb and benzo(a)pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, total Hg ≤ 1 ppm.	
126a	Carbon black	77266 (nano) Carbon Black (nano)	1333-86-4, 7440-44-0	215-609-9, 231-153-3, 931-328-0, 931-334-3	Black		10 %	Not to be used in applications that may lead to exposure	