Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2016/621. (See end of Document for details)

ANNEX

The following entries are added to Annex VI to Regulation (EC) No 1223/2009 as reference numbers 30 and 30a:

ReferenceSubstance identification					Conditions			Wording
number	Chemic name/ INN	al Name of Common Ingredie Glossary	nts	EC number	Product type, body parts	Maximu concentr in ready for use prepara	ration	of conditions of use and warnings
a	b	c	d	e	f	g	h	i
' 30	Zinc oxide	Zinc Oxide	1314-13-2	2215-222-5	5	25 % ^a	Not to be used in application that may lead to exposure of the enduser's lungs by inhalation	
30a	Zinc oxide	Zinc Oxide (nano)	1314-13-2	2215-222-5		25 %ª		ı. rials

a In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column g.'

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				crystalline
				structure
				and
				physical
				appearance
				as
				clusters
				that
				are
				rod-
				like,
				star-
				like
				and/
				or
				isometric
				shapes,
				with
				impurities
				consisting
				only
				of
				carbon
				dioxide
				and
				water,
				whilst
				any
				other
				impurities
				are
				less
				than
				1
				%
				in
				total,
				median
				diameter
				of
				the
				particle
				number
				size
				distribution
				D50
				(50
				% of
				the
				number
				below

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this diameter) > 30 nm and D1 (1 % below this size) > 20 nm, — water solubility < 50 mg/ L — uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethe cross- polymer, or octyl triethoxy silane.					
> 30 nm and D1 (1 % below this size) > 20 nm, — water solubility < 50 mg/ L — uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethicone, dimethoxydiphenylsilanetriethe cross- polymer, or octyl triethoxy			'		this
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— uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethocross-polymer, or octyl triethoxy					
or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetrietho cross- polymer, or octyl triethoxy					
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