

ANNEX VII

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

For the purpose of this Directive, UV filters are substances which, contained in cosmetic sunscreen products, are specifically intended to filter certain UV rays in order to protect the skin from certain harmful effects of these rays.

These UV filters may be added to other cosmetic products within the limits and under the conditions laid down in this Annex.

Other UV filters used in cosmetic products solely for the purpose of protecting the product against UV rays are not included in this list.

Warning which must be printed on the label 'Do not stay too long in the sun, even while using a sunscreen product' (for primary sunscreen products)

ANNEX VII - PART 1

LIST OF PERMITTED UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

Annex VII - List of UV filters which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
A28	Menthyl anthranilate	5 %		
A29	Zinc oxide	25 % ⁽²⁾	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.	

Annex VII - List of UV filters which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
A29a	Zinc Oxide (nano)	25% ⁽²⁾	<p>Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.</p> <p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> • purity ≥ 96% with wurtzite 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 other impurities are less than 1% in total. • Median diameter of the particle number size distribution D50 (50% of the number below this diameter) > 30 nm and D1 (1% below this size) >20nm. • Water solubility < 50 mg/l. <p>Coating materials can be used that have been demonstrated to be safe and not to affect the nanoparticle properties related to the behaviour and/or effects</p>	
1	Entry deleted			
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene methyl) anilinium methyl sulphate	6%		
3	Homosalate (INN)	10%		
4	Oxybenzone (INN)	6%		Contains oxybenzone ⁽¹⁾
5	Entry deleted			
6	2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8% expressed as acid		

Annex VII - List of UV filters which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
7	3,3'-(1,4-Phenylenedimethylene)bis(7,7-dimethyl-2-oxo-bicyclo-[2,2,1]hept-1-yl methanesulfonic acid) and its salts	10% (expressed as acid)		
8	1-(4-Tert-Butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione	5%		
9	alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts	6% (expressed as acid)		
10	2-Cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester (Octocrylene)	10% (expressed as acid)		
11	Polymer of N-((2 and 4)-[2-oxoborn-3-ylidene) methyl] benzyl] acrylamide	6%		
12	Octyl methoxycinnamate	10%		
13	Ethoxylated Ethyl-4-aminobenzoate (PEG-25 PABA)	10%		
14	Isopentyl-4-methoxycinnamate (Isoamyl p-methoxycinnamate)	10%		
15	2,4,6-Trianiino-(p-carbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine (Octyl triazone)	5%		
16	Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethylsilyloxy)-disiloxanyl)propyl (Drometrizole Trisiloxane)	15%		
17	Benzoic acid, 4,4-(((6-(((1,1-dimethylethyl)amino) carbonyl)phenyl)amino)-1,3,5-triazine-2,4-diyl)diimino)bis-,bis-(2-ethylhexyl)ester)	10%		
18	3-(4'-Methylbenzylidene)-dl-camphor (4-Methylbenzylidene Camphor)	4%		

Annex VII - List of UV filters which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
19	<i>Entry Deleted</i>			
20	2-Ethylhexyl salicylate (Octyl Salicylate)	5%		
21	4-Dimethylaminobenzoate of ethyl-2-hexyl (octyl dimethyl PABA)	8%		
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-4) and its sodium salt (Benzophenone-5)	5% (of acid)		
23	2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol);2,2'-Methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (Methylene Bis-Benzotriazolyl Tetramethylbutylphenol/MBBT) CAS 103597-45-1	10% ⁽⁵⁾		
23a	2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol);2,2'-Methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano)/MBBT (nano)) CAS 103597-45-1	10% ⁽⁵⁾	<p>Not to be used in applications that may lead to exposure of the end user's lungs by inhalation.</p> <p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> - Purity ≥ 98.5 %, with 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(isooctyl)phenol) isomer fraction not exceeding 1.5 %; - Solubility < 5 ng/L in water at 25 °C; - Partition coefficient (Log Pow): 12.7 at 25 °C; - Uncoated; - Median particle size D50 (50% of number below this diameter): ≥ 120 nm of mass distribution and/or ≥ 60 nm of number size distribution. 	

Annex VII - List of UV filters which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
24	Monosodium salt of 2,2'-(1,4-phenylene)bis-1H-benzimidazole-4,6-disulphonic acid	10% (of acid)		
25	(1,3,5)-Triazine-2,4-bis-[[4-(2-ethyl-hexyloxy)-2-hydroxy]-phenyl]-6-(4-methoxyphenyl)	10%		
26	Dimethicodiethylbenzalmalonate (CAS No 207574-74-1)	10 %		
27	Titanium dioxide ⁽³⁾ (CAS No 13463-67-7/1317-70-0/1317-80-2)	25 % ⁽⁴⁾	Titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$, to be used in compliance with Annex III, No [338]. For the product types under letter (c) of column (c) in Annex III, No [338], the maximum concentration in ready for use preparation provided in column (d) of this entry applies.	

Annex VII - List of UV filters which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
27a	Titanium dioxide (nano)	25 % ⁽⁴⁾	<p>Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.</p> <p>Only nanomaterials having the following characteristics are allowed:</p> <ul style="list-style-type: none"> - Purity \geq 99% - Rutile form, or rutile with up to 5% anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes, - Median particle size based on number size distribution \geq 30 nm, - Aspect ratio from 1 to 4.5 and volume specific surface area \leq 460 m²/cm³, - Coating materials can be used that have been demonstrated to be safe and not to affect the nanoparticle properties related to the behaviour and/or effects, - Photocatalytic activity \leq 10% compared with corresponding non-coated or non-doped reference, - Nanoparticles are photostable in the final formulation. 	
28	<p>Benzoic acid, 2-[-4-(diethylamino)-2-hydroxybenzoyl]-, hexylester.</p> <p>INCI Name: Diethylamino hydroxybenzoyl hexyl Benzoate</p> <p>CAS No 302776-68-7</p>	10 %		

Annex VII - List of UV filters which cosmetic products may contain

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
29	1,3,5-Triazine, 2,4,6-tris [1,1'-biphenyl]-4-yl-, including as nanomaterial. INCI Name : Tris-biphenyl triazine Tris-biphenyl triazine (nano) CAS No. 31274-51-8	10%	Not to be used in sprays. Only nanomaterials having the following characteristics are allowed: — median primary particle size > 80 nm; — Purity ≥ 98 %; — Uncoated	
30	3,3-(1,4-Phenylene) bis (5,6-diphenyl- 1,2,4-triazine) CAS 5514-22-2	5%	Not to be used in application that may lead to exposure of the end user's lungs by inhalation.'	
31	2-ethoxyethyl (2Z)-2-cyano- 2-[3-(3-methoxypropylamino) cyclohex-2-en-1-ylidene]acetate Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate CAS No 1419401-88-9	3 %	-- Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation — Do not use with nitrosating agents – Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers'	

1. Not required if concentration is 0.5 % or less and when it is used only for product protection purposes
2. In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column c.
3. For use of titanium dioxide as a colourant see Annex IV, CI 77891
4. In case of combined use of titanium dioxide and titanium dioxide (nano), the sum shall not exceed the limit given in column c.
5. In case of combined use of Methylene Bis-Benzotriazolyl Tetramethylbutylphenol and Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano), the sum shall not exceed the limit given in column c.