

Sunscreen regulations: an updated comparison

Shown here are details of sunscreen regulations applying in Japan, the United States, Canada, the European Union, South Africa, Australia and New Zealand, South Korea, China and Thailand. Harmonisation still has not been achieved either in the composition of approved sunscreens or in the maximum content of individual ingredients. Also remaining not standardised is the test method used to calculate the Sun Protection Factor (SPF).

Ingredients which have limitations in combinations in all cosmetics. Not applied on mucous membrane and rinsed off.						Ingredients which have limitations in combinations in all cosmetics. Not applied on mucous membrane and NOT rinsed off. Mucous membrane.		
Sunscreens for Japan			1	2	3	Sunscreens for US	Canada	
	All cosmetics					Permitted active ingredients	Maximum concentration %	Ref No
Benzophenone-1 (Dihydroxybenzophenone)			1.00	10.00	Note 4			
Benzophenone-2 (Tetrahydroxybenzophenone)			1.00	10.00	0.05			
Benzophenone-3 (Oxybenzone)			No limit	5.00	5.00	Oxybenzone	6.00	6.00
Benzophenone-4 (Sulisobenzone)		Note 6	1.00	10.00	0.10	Sulisobenzone	10.00	10.00
Benzophenone-5			1.00	10.00	Note 4			22
Benzophenone-6 (Dihydroxy Dimethoxy Benzophenone)			1.00	10.00	Note 4			
Benzophenone-8 (Dioxybenzone)						Dioxybenzone	3.00	3.00
Benzophenone-9 (Sodium Dihydroxy Dimethoxy Disulfobenzophenone)			1.00	10.00	Note 4			
3-Benzylidene Camphor								19
Benzylidene Camphor Sulfonic Acid								9
Bis-Ethylhexyloxyphenolmethoxyphenyl Triazine								25
Butyl Methoxydibenzoylmethane (Avobenzone)			10.00	10.00	0.10	Avobenzone	3.00	5.00
Butyl PABA	4.00	As total						
Camphor Benzalkonium Methosulfate								2
Cinoxate			No limit	5.00	5.00	Cinoxate	3.00	3.00
DEA Methoxycinnamate								10.00
Diethylamino Hydroxy Benzoyl Hexyl Benzoate								28
Diethylhexyl Butamido Triazone								17
Digalloyl Trioleate								
Diisopropyl Methyl Cinnamate			0.50	10.00	Note 4			
1-(3,4-Dimethoxyphenyl)-4,4-Dimethyl-1,3-Pentadiene			Note 4	7.00	Note 4			
Disodium Phenyl Dibenzimidazole Tetrasulfonate								24

Additional information

Not allowed.

Japan

Note 4: No combination is allowed.

Note 5: Refers to items containing 72.0%-79.0% of isopropyl p-methoxycinnamate, 15.0%-21.0% of ethyl 2,4-diisopropylcinnamate and 3.0%-9.0% of methyl 2,4-diisopropylcinnamate.

Note 6: Total amount as hydroxymethoxybenzophenone sulfonic acid.

United States**Products with combinations of active ingredients:**

- The concentration of each active ingredient must be sufficient to produce a minimum SPF of 2 (in the finished product).
- The finished product must have an SPF of not less than the number of active ingredients multiplied by 2.

- Zinc oxide may be used in combination with any monograph sunscreen active except avobenzone.

Labelling:

- The FDA has established 30 as an upper limit for SPF labelling. Products with SPF values over 30 may be labelled as "30 plus" or "30+".
- The SPF value for a product labelled "water resistant" or "very water resistant" will be the SPF determined in the water resistance test.
- Extended wear claims concerning a specific number of hours of protection and the use of terms such as "all day protection" are not permitted.
- Permissible labelling is limited to prevention of sunburn.

European Union

*Contains oxybenzone.

(Not required when concentration is not more than 0.5%, and when the substance is only intended to protect the product).

Sunscreens for EU	Maximum concentration %	South Africa	Australia and New Zealand	South Korea	China	Thailand
		10.00		10.00		
		10.00				
Oxybenzone (INN) [Benzophenone-3]*	10.00	10.00	10.00	10.00	10.00	10.00
2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid [Benzophenone-4] and its sodium salt [Benzophenone-5] (Sulisobenzene (INN) and Sulisobenzene sodium (INN))	5.00 Expressed as acid	10.00	10.00		5.00	10.00
2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid [Benzophenone-4] and its sodium salt [Benzophenone-5] (Sulisobenzene (INN) and Sulisobenzene sodium (INN))	5.00 Expressed as acid	5.00	10.00		5.00	5.00
		5.00				
		3.00	3.00			3.00
		No maximum specified				
3-Benzylidenebornan-2-one [3-Benzylidene camphor]	2.00	2.00			2.00	2.00
α -(2-Oxoborn-3-ylidene)toluene-4-sulphonic acid [Benzylidene camphor sulfonic acid] and its salts	6.00 Expressed as acid	6.00	6.00		6.00	6.00
5,5'-Bis(2-ethylhexyloxy)-2,2'-(6-methoxyphenyl)-1,3,5-triazine-2,4-diyl diphenol	10.00	10.00	10.00		10.00	10.00
1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl)-propane-1,3-dione (Avobenzone (INN)) [Butyl methoxy dibenzoylmethane]	5.00	5.00	5.00	5.00	5.00	5.00
N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl)anilinium methyl sulphate [Camphor benzalkonium methosulfate]	6.00	6.00	6.00		6.00	6.00
		5.00	6.00	5.00		
		8.00 As the acid		8.00 As the acid		
Diethylamino Hydroxy Benzoyl Hexyl Benzoate	10.00				10.00	
Bis(2-ethylhexyl) 4,4'-[6-tertbutylcarbamoylanilino]-1,3,5-triazine-2,4-diylidimino]dibenzoate	10.00	10.00			10.00	10.00
		5.00		5.00		5.00
		10.00				
		7.00				
diSodium 2,2'-(1,4-phenylene)bis(1Hbenzimidazole-4,6-disulfonate)	10.00 Expressed as acid	10.00	10.00	10.00	10.00	10.00

REGULATIONS

Ingredients which have limitations in combinations in all cosmetics.										
Sunscreens for Japan						Suncreens for US			Canada	
	All cosmetics		1	2	3	Permitted active ingredients	Maximum concentration %		Ref No	
Drometrizole				7.00						
Drometrizole Trisiloxane				10.00					16	
Ethyl Dihydroxypropyl PABA								5.00		
Ethylhexyl Dimethoxy Benzylidene Dioximidazoline Propionate				3.00						
Ethyl Diisopropylcinnamate		Note 5	0.10	10.00	Note 4					
Ethylhexyl Dimethoxybenzylidene Dioximidazolidine Propionate			3.00	3.00	Note 4					
Ethylhexyl Dimethyl PABA (Padimate O)			10.00	10.00	1.00	Padimate O	8.00	8.00	21	
Ethylhexyl Methoxycinnamate			12.00	20.00	1.00	Octyl methoxycinnamate Octinoxate	7.50	8.50	12	
Ethylhexyl Salicylate (Octyl Salicylate)			5.00	10.00	Note 4	Octyl Salicylate Octisalate	5.00	6.00	20	
Ethylhexyl Triazone			3.00	3.00	Note 4				15	
Ethyl PABA	4.00	As total								
Ferulic Acid			No data	10.00	No data					
4-(2-Beta-Glucopyranosiloxy) Propoxy-2-Hydroxybenzophenone			No data	5.00	No data					
Glyceryl Ethylhexanoate Dimethoxycinnamate			10.00	10.00	0.10					
Glyceryl PABA	4.00	As total						3.00		
Homosalate (Homomenthyl Salicylate)			10.00	10.00	Note 4	Homosalate	15.00	15.00	3	
Isoamyl p-Methoxycinnamate				10.00					14	
Isopentyl Trimethoxycinnamate Trisiloxane			7.50	7.50	Note 4					
Isopropylbenzyl Salicylate										
Isopropyl Methoxycinnamate		Note 5	0.10	10.00	Note 4					
Lawsone and Dihydroxyacetone										
Menthyl anthranilate						Menthyl anthranilate	5.00	5.00		
4-Methylbenzylidene Camphor								6.00	18	
Methylene Bis-Benzotriazolyl Tetramethylbutylphenol				10.00					23	
Octocrylene						Octocrylene	10.00	12.00	10	
PABA	4.00	As total				Aminobenzoic acid	15.00	15.00	1	
PEG-25 PABA									13	
Pentyl Dimethyl PABA (Amyl p-Dimethylamino PABA)			0.10	10.00	Note 4					
Phenylbenzimidazole Sulfonic Acid			3.00	3.00	Note 4	Phenylbenzimidazole Sulfonic Acid Ensulizole	4.00	8.00	6	
Polyacrylamido Methylbenzylidene Camphor									11	
Polysilicone-15				10.00					26	
TEA Salicylate – see Trolamine Salicylate										
Terephthalidene Dicamphor Sulfonic Acid				10.00				10.00	7	
Titanium dioxide				No limit		Titanium dioxide	25.00	25.00	27	
Trolamine Salicylate						Trolamine Salicylate	12.00	12.00		
Zinc oxide				No limit		Zinc oxide	25.00	20.00		

REGULATIONS

Sunscreens for EU		South Africa	Australia and New Zealand	South Korea	China	Thailand
	Maximum concentration %					
2-(2H-Benzotriazol-2-yl)-4-methyl-6-[2-methyl-3-[1,3,3,3-tetramethyl-1-(trimethylsilyloxy)-disiloxan-1-yl]propyl]phenol [Drometrizole trisiloxane]	15.00	15.00	15.00		15.00	15.00
		5.00		5.00		
		3.00				
2-Ethylhexyl 4-dimethylaminobenzoate [Octyl dimethyl PABA]	8.00	8.00	8.00	8.00	8.00	8.00
2-Ethylhexyl 4-methoxycinnamate [Octyl methoxycinnamate]	10.00	10.00	10.00	7.50	10.00	10.00
2-Ethylhexyl salicylate [Octyl salicylate]	5.00	5.00	5.00	5.00	5.00	5.00
Tris(2-ethylhexyl) 4,4'4''-(1,3,5-triazine-2,4,6-triyltriamino)tribenzoate [Octyl triazone]	5.00	5.00	5.00	5.00	5.00	5.00
		10.00				
		5.00				
		10.00				
		5.00		3.00		3.00
Homosalate (INN)	10.00	10.00	15.00	10.00	10.00	10.00
Isopentyl 4-methoxycinnamate [Isoamyl p-methoxycinnamate]	10.00	10.00	10.00	10.00	10.00	10.00
		7.50				
		4.00				
		10.00				
		5.00	5.00	5.00		5.00
3-(4-Methylbenzylidene)borman-2-one [4-Methylbenzylidene camphor]	4.00	4.00	4.00	4.00	4.00	4.00
2-2'-Methylenebis[6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol]	10.00	10.00	10.00	10.00	10.00	10.00
2-Ethylhexyl 2-cyano-3,3-diphenylacrylate [Octocrylene]	10.00	10.00	10.00	10.00	10.00	10.00
	Expressed as acid					
4-Aminobenzoic acid [PABA]	5.00	15.00	15.00	5.00	5.00	5.00
Ethoxylated ethyl-4-aminobenzoate [PEG-25 PABA]	10.00	10.00	10.00		10.00	10.00
				5.00		
2-Phenylbenzimidazole-5-sulphonic acid [Phenylbenzimidazole sulfonic acid] and its potassium, sodium and triethanolamine salts	8.00	8.00	4.00	4.00	8.00	8.00
	Expressed as acid					
Polymer of N-[(2 and 4)-[2-oxoborn-3-ylidene)methyl]benzyl]acrylamide [Polyacrylamidomethyl benzylidene camphor]	6.00	6.00			6.00	6.00
α -(Trimethylsilyl)-w-(trimethylsilyloxy) poly-[oxy(dimethyl)silylene]-co-[oxy(methyl)(2-[p-[2,2-bis(ethoxycarbonyl)vinyl]phenoxy]-1-methyleneethyl)silylene]-co-[oxy(methyl)(2-[p-[2,2-bis(ethoxycarbonyl)vinyl]phenoxy]prop-1-enyl)silylene] where there are usually 60 polymeric units, of which the first part of the copolymer provides 56 (Dimethicodiethylbenzylmalonate) (CAS No. 207574-74-1)	10.00	10.00	10.00		10.00	
3,3-(1,4-Phenylenedimethylene)bis(7,7-dimethyl-2-oxobicyclo[2.2.1]hept-1-ylmethanesulfonic acid) [Terephthalylidene dicamphor sulfonic acid] and its salts	10.00	10.00	10.00		10.00	10.00
	Expressed as acid					
Titanium dioxide	25.00	25.00	25.00	25.00	25.00	
		12.00	12.00			12.00
		25.00	20.00	25.00	25.00	