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ANNEX V

LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS

Preamble

1. For the purposes of this list:

- ‘Salts’ is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.
- ‘Esters’ is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.

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2. All finished products containing substances in this Annex and which release formaldehyde must be labelled with the warning ‘contains formaldehyde’ where the concentration of formaldehyde in the finished product exceeds 0,05 %

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Reference number	Substance identification				Conditions			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
1	Benzoic acid and its sodium salt	Benzoic acid Sodium Benzoate	65-85-0 532-32-1	200-618-2 208-534-8	Rinse-off products, except oral products Oral products Leave-on products	2,5 % (acid) 1,7 % (acid) 0,5 % (acid)		
1a	Salts of benzoic acid other than that listed under reference number 1 and esters of benzoic acid	Ammonium benzoate, calcium benzoate, potassium benzoate, magnesium benzoate, MEA-benzoate, methyl benzoate, ethyl benzoate, propyl benzoate, butyl benzoate, isobutyl benzoate, isopropyl benzoate, phenyl benzoate	1863-63-4, 2090-05-3, 582-25-2, 553-70-8, 4337-66-0, 93-58-3, 93-89-0, 2315-68-6, 136-60-7, 120-50-3, 939-48-0, 93-99-2	217-468-9, 218-235-4, 209-481-3, 209-045-2, 224-387-2, 202-259-7, 202-284-3, 219-020-8, 205-252-7, 204-401-3, 213-361-6, 202-293-2		0,5 % (acid)		

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Reference number	Substance identification				Conditions			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
2	Propionic acid and its salts	Propionic acid, ammonium propionate, calcium propionate, magnesium propionate, potassium propionate, sodium propionate	79-09-4, 17496-08-1, 4075-81-4, 557-27-7, 327-62-8, 137-40-6	201-176-3, 241-503-7, 223-795-8, 209-166-0, 206-323-5, 205-290-4		2 % (acid)		
3	Salicylic acid ⁽¹⁾ and its salts	Salicylic acid Calcium salicylate, magnesium salicylate, MEA- salicylate, sodium salicylate, potassium salicylate, TEA- salicylate	69-72-7 824-35-1, 18917-89-0, 59866- 70-5, 54-21-7, 578-36-9, 2174-16-5	200-712-3 212-525-4, 242-669-3, 261-963-2, 200-198-0, 209-421-6, 218-531-3		0,5 % (acid) 0,5 % (acid)	Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.	Not to be used for children under 3 years of age ⁽¹²⁾ Not to be used for children under 3 years of age ⁽²⁾
4	Hexa-2,4-dienoic acid and its salts	Sorbic acid, calcium sorbate, sodium sorbate, potassium sorbate	110-44-1, 7492-55-9, 7757-81-5, 24634-61-5	203-768-7, 231-321-6, 231-819-3, 246-376-1		0,6 % (acid)		

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Reference number	Substance identification				Conditions			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
6	Moved or deleted							
7	Biphenyl-2-ol ⁽¹⁹⁾	o-Phenylphenol	90-43-7	201-993-5	(a) Rinse-off Products (b) Leave-on products	(a) 0,2 % (as phenol) (b) 0,15 % (as phenol)		Avoid contact with eyes
8	Pyrithione zinc ⁽⁴⁾	Zinc pyrithione	13463-41-7	236-671-3	Hair products Other products	1,0 % 0,5 %	Only in rinse-off products Not to be used in oral products	
9	Inorganic sulphites and hydrogen-sulphites ⁽⁵⁾	Sodium sulfite, ammonium bisulfite, ammonium sulfite, potassium sulfite, potassium hydrogen sulfite, sodium bisulfite, sodium metabisulfite, potassium metabisulfite	7757-83-7, 10192-30-0, 10196-04-0, 10117-38-1, 7773-03-7, 7631-90-5, 7681-57-4, 16731-55-8	231-821-4, 233-469-7, 233-484-9, 233-321-1, 231-870-1, 231-548-0, 231-673-0, 240-795-3		0,2 % (as free SO ₂)		
10	Moved or deleted							
11	Chlorobutanol	Chlorobutanol	57-15-8	200-317-6		0,5 %	Not to be used in aerosol dispensers (sprays)	Contains Chlorobutanol

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Reference number	Substance identification				Conditions			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
12	4-Hydroxybenzoic acid and its Methyl- and Ethyl-esters, and their salts	4-Hydroxybenzoic acid methylparaben potassium ethylparaben potassium paraben sodium methylparaben sodium ethylparaben ethylparaben sodium paraben potassium methylparaben calcium paraben	99-96-7 99-76-3 36457-19-9 16782-08-4 5026-62-0 35285-68-8 120-47-8 114-63-6 26112-07-2 69959-44-0	202-804-9 202-785-7 253-048-1 240-830-2 225-714-1 252-487-6 204-399-4 204-051-1 247-464-2 274-235-4		0,4 % (as acid) for single ester 0,8 % (as acid) for mixtures of esters		
12a	Butyl 4-hydroxybenzoate and its salts Propyl 4-hydroxybenzoate and its salts	Butylparaben propylparaben sodium propylparaben sodium butylparaben potassium butylparaben potassium propylparaben	94-26-8 94-13-3 35285-69-9 36457-20-2 38566-94-8 84930-16-5	202-318-7 202-307-7 252-488-1 253-049-7 254-009-1 284-597-5		0,14 % (as acid) for the sum of the individual concentrations 0,8 % (as acid) for mixtures of substances mentioned in entry 12 and 12a, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0,14 %	Not to be used in leave-on products designed for application on the nappy area of children under three years of age.	For leave-on products designed for children under three years of age: 'Do not use on the nappy area'

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Reference number	Substance identification				Conditions			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
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione and its salts	Dehydroacetic acid, sodium dehydroacetate	520-45-6, 4418-26-2, 16807-48-0	208-293-9, 224-580-1		0,6 % (as acid)	Not to be used in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt	Formic acid, sodium formate	64-18-6, 141-53-7	200-579-1, 205-488-0		0,5 % (as acid)		
15	3,3'-Dibromo-4,4'-hexamethylene-dioxydi-benzamidine and its salts (including isethionate)	Dibromohexamidine Isethionate	93856-83-8	299-116-4		0,1 %		
16	Thiomersal	Thimerosal	54-64-8	200-210-4	Eye products	0,007 % (of Hg) If mixed with other mercurial compounds authorised by this Regulation, the maximum concentration of Hg remains fixed at 0,007 %		Contains Thiomersal
17	Phenylmercuric salts (including borate)	Phenyl Mercuric Acetate, Phenyl Mercuric Benzoate	62-38-4, 94-43-9	200-532-5, 202-331-8	Eye products	0,007 % (of Hg) If mixed with other mercurial compounds authorised by this Regulation, the maximum concentration of Hg remains fixed at 0,007 %		Contains Phenylmercuric compounds

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	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
18	Undec-10-enoic acid and its salts	Undecylenic acid, potassium undecylenate, sodium undecylenate, calcium undecylenate, TEA-undecylenate, MEA-undecylenate	112-38-9, 6159-41-7, 3398-33-2, 1322-14-1, 84471-25-0, 56532-40-2	203-965-8, 222-264-8, 215-331-8, 282-908-9, 260-247-7		0,2 % (as acid)		
19	5- Pyrimidinamine, 1,3-bis (2-ethylhexyl) hexahydro-5-methyl-	Hexetidine	141-94-6	205-513-5		0,1 %		
20	5-Bromo-5-nitro-1,3-dioxane	5-Bromo-5-nitro-1,3-dioxane	30007-47-7	250-001-7	Rinse-off products	0,1 %	Avoid formation of nitrosamines	
21	Bronopol	2-Bromo-2-nitropropane-1,3-diol	52-51-7	200-143-0		0,1 %	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol	Dichlorobenzyl Alcohol	1777-82-8	217-210-5		0,15 %		
23	1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl) urea (6)	Triclocarban	101-20-2	202-924-1		0,2 %	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene <1 ppm 3,3',4,4'-Tetrachloroazoxybenzene <1 ppm	

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	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
24	Chlorocresol	p-Chloro-m-Cresol	59-50-7	200-431-6	Not to be used in products applied on mucuous membranes	0,2 %		
25	5-Chloro-2- (2,4-dichlorophenoxy) phenol	Triclosan	3380-34-5	222-182-2	(a) Toothpastes Hand soaps Body soaps/ Shower gels Deodorants (non-spray) Face powders and blemish concealers Nail products for cleaning the fingernails and toenails before the application of artificial nail systems (b) Mouthwashes	(a) 0,3 % (b) 0,2 %		

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Reference number	Substance identification				Conditions			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
26	Chloro-xyleneol	Chloroxylenol	88-04-0	201-793-8		0,5 %		
27	N,N"-methylene-bis[N'-(3-(hydroxymethyl)-2,5-dioximidazolidin-4-yl)urea]	Imidazolidinyl urea	39236-46-9	254-372-6		0,6 %		
28	Polyhexamethylene biguanide hydrochloride	Polyaminopropyl biguanide	32289-58-0, 27083-27-8, 28757-47-3, 133029-32-0	608-723-9 608-042-7		0,1 %	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation	
29	2-Phenoxyethanol	Phenoxyethanol	122-99-6	204-589-7		1,0 %		
30	Methenamine	Methenamine	100-97-0	202-905-8		0,15 %		
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Reference number	Substance identification				Conditions			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
▼ <u>M29</u> 32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one ⁽²⁰⁾	Climbazole	38083-17-9	253-775-4	(a) Hair lotions ⁽²¹⁾ (b) Face creams ⁽²¹⁾ (c) Foot care products ⁽²¹⁾ (d) Rinse-off shampoo ⁽²¹⁾	(a) 0,2 % ⁽²¹⁾ (b) 0,2 % ⁽²¹⁾ (c) 0,2 % ⁽²¹⁾ (d) 0,5 % ⁽²¹⁾		
▼ <u>B</u> 33	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	DMDM Hydantoin	6440-58-0	229-222-8		0,6 %		
▼ <u>M1</u> 34	Benzyl alcohol ⁽⁷⁾	Benzyl Alcohol	100-51-6	202-859-9		1,0 %		
▼ <u>B</u> 35	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl) 2-pyridon, Piroctone Olamine	50650-76-5, 68890-66-4	272-574-2	Rinse-off products Other products	1,0 % 0,5 %		
36	Moved or deleted							
37	2,2'-methylenebis(6-bromo-4-chlorophenol)	Bromochlorophene	15435-29-7	239-446-8		0,1 %		
38	4-Isopropyl-m-cresol	o-Cymen-5-ol	3228-02-2	221-761-7		0,1 %		

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	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
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one	Methylchloroisothiazolinone (and) Methylisothiazolinone ⁽¹⁷⁾	26172-55-4, 2682-20-4, 55965-84-9	247-500-7, 220-239-6	Rinse-off products	0,0015 % (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3(2H)-one)		
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42	N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine and its digluconate, diacetate and dihydrochloride	Chlorhexidine, Chlorhexidine Diacetate, Chlorhexidine Digluconate, Chlorhexidine Dihydrochloride	55-56-1, 56-95-1, 18472-51-0, 3697-42-5	200-238-7, 200-302-4, 242-354-0, 223-026-6		0,3 % (as chlorhexidine)		
43	1-Phenoxypropan-2-ol ⁽⁸⁾	Phenoxyisopropanol	770-35-4	212-222-7	Only for rinse-off products	1,0 %		
44	Alkyl (C ₁₂₋₂₂) trimethyl ammonium bromide and chloride	Behentrimonium chloride ⁽¹⁵⁾ , cetrimonium bromide, cetrimonium chloride ⁽¹⁶⁾ , laurrimonium bromide, laurrimonium chloride,	17301-53-0, 57-09-0, 112-02-7, 1119-94-4, 112-00-5,	241-327-0, 200-311-3, 203-928-6, 214-290-3, 203-927-0,		0,1 %		

▼ M7▼ M30▼ B▼ M6▼ C2

▼ C2

Reference number	Substance identification				Conditions			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
		steartrimonium bromide, steartrimonium chloride ⁽¹⁶⁾	1120-02-1, 112-03-8	214-294-5, 203-929-1				
45	4,4-Dimethyl-1,3-oxazolidine	Dimethyl Oxazolidine	51200-87-4	257-048-2		0,1 %	pH > 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	Diazolidinyl Urea	78491-02-8	278-928-2		0,5 %		
47	Benzenecarboximidamide, 4,4'-(1,6-hexanediylbis (oxy))bis- and its salts (including isethionate and p-hydroxybenzoate)	Hexamidine, Hexamidine diisethionate, Hexamidine paraben	3811-75-4, 659-40-5, 93841-83-9	211-533-5, 299-055-3		0,1 %		
48	Glutaraldehyde (Pentane-1,5-dial)	Glutaral	111-30-8	203-856-5		0,1 %	Not to be used in aerosols (sprays)	Contains glutaral ⁽⁹⁾
49	5-Ethyl-3,7-dioxo-1-azabicyclo [3.3.0] octane	7-Ethylbicyclo-oxazolidine	7747-35-5	231-810-4		0,3 %	Not to be used in oral products and in products applied on mucous membranes	
50	3-(p-Chlorophenoxy)-propane-1,2 diol	Chlorphenesin	104-29-0	203-192-6		0,3 %		

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Reference number	Substance identification				Conditions			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
51	Sodium hydroxy-methylamino acetate	Sodium Hydroxy-methylglycinate	70161-44-3	274-357-8		0,5 %		
52	Silver chloride deposited on titanium dioxide	Silver chloride	7783-90-6	232-033-3		0,004 % (as AgCl)	20 % AgCl (w/w) on TiO ₂ . Not to be used in products for children under 3 years of age, in oral products and in eye and lip products	
53	Benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride	Benzethonium Chloride	121-54-0	204-479-9	(a) Rinse-off products (b) Leave-on products other than oral products	0,1 %		
54	Benzalkonium chloride, bromide and saccharinate ⁽¹⁰⁾	Benzalkonium chloride, benzalkonium bromide, benzalkonium saccharinate	8001-54-5, 63449-41-2, 91080-29-4, 68989-01-5, 68424-85-1, 68391-01-5, 61789-71-7, 85409-22-9	264-151-6, 293-522-5, 273-545-7, 270-325-2, 269-919-4, 263-080-8, 287-089-1		0,1 % (as benzalkonium chloride)		Avoid contact with eyes

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Reference number	Substance identification				Conditions			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
55	Methanol, (phenylmethoxy-)	Benzylhemiformal	14548-60-8	238-588-8	Rinse-off products	0,15 %		
56	3-Iodo-2-propynylbutylcarbamate	Iodopropynyl butylcarbamate	55406-53-6	259-627-5	(a) Rinse-off products (b) Leave-on products (c) Deo-dorants/ anti-perspirants	(a) 0,02 % (b) 0,01 %, (c) 0,0075 %	Not to be used in oral and lip products (a) Not to be used in products for children under 3 years of age, except in bath products/ shower gels and shampoo (b) Not to be used in body lotion and body cream ⁽¹³⁾ (b) and (c) Not to be used in products for children under 3 years of age	(a) Not to be used for children under 3 years of age ⁽¹¹⁾ (b) and (c) Not to be used for children under 3 years of age ⁽¹²⁾

▼ **B**

Reference number	Substance identification				Conditions			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
57	2-Methyl-2H-isothiazol-3-one	Methylisothiazolinone ⁽¹⁸⁾	2682-20-4	220-239-6	Rinse-off products	0,0015 %		
58	Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride ⁽¹⁴⁾	Ethyl Lauroyl Arginate HCl	60372-77-2	434-630-6	(a) Mouthwashes (b) Other products	(a) 0,15 % (b) 0,4 %	(a) Not to be used in preparations for children under 10 years of age (b) Not to be used in lip products, oral products (other than mouthwashes), and spray products	(a) Not to be used for children under 10 years of age
59	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, silver(1+) salt, monohydrate	Citric acid (and) Silver citrate	—	460-890-5		0,2 %, corresponding to 0,0024 % of silver	Not to be used in oral products and eye products	

▼ **M6**▼ **C2**

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Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
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a	b	c	d	e	f	g	h	i
60	4-(3-ethoxy-4-hydroxyphenyl)butan-2-one	Hydroxyethoxyphenyl Butanone	569646-79-3	933-435-8		0,7 %		

▼ **M33**▼ **B**

(¹) For uses other than preservative, see Annex III, No 98.

(²) Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.

(³) ► **M30** ——— ◀

(⁴) For use other than as a preservative, see Annex III, No. 101.

(⁵) For use other than as a preservative, see Annex III, No. 99.

(⁶) For use other than as a preservative, see Annex III, No. 100.

► **M1** (⁷) For other uses than preservatives, see Annex III, entry No 45. ◀

(⁸) For use other than as a preservative, see Annex III, No. 54.

(⁹) Only if the concentration exceeds 0,05 %.

(¹⁰) For use other than as a preservative, see Annex III, No. 65.

(¹¹) Solely for products, other than bath products/shower gels and shampoo, which might be used for children under 3 years of age.

(¹²) Solely for products which might be used for children under 3 years of age.

(¹³) Concerns any products aimed to be applied on a large part of the body.

► **M15** (¹⁴) For other uses than preservatives, see Annex III, entry No 197. ◀

► **M6** ► **C2** (¹⁵) For use other than as a preservative, see Annex III, No 287.

(¹⁶) For use other than as a preservative, see Annex III, No 286. ◀ ◀

► **M7** (¹⁷) Methylisothiazolinone is also regulated in entry 57. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product. ◀

► **M20** (¹⁸) Methylisothiazolinone is also regulated in entry 39 of Annex V in a mixture with methylchloroisothiazolinone. The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product. ◀

► **M26** (¹⁹) From 17 June 2019 cosmetic products containing Biphenyl-2-ol and not complying with those conditions shall not be placed on the Union market. From 17 September 2019 cosmetic products containing Biphenyl-2-ol and not complying with those conditions shall not be made available on the Union market. ◀

► **M29** (²⁰) For use other than as a preservative, see Annex III, entry 310.

(²¹) From 27 November 2019 cosmetic products containing 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one and not complying with those conditions shall not be placed on the Union market. From 27 February 2020 cosmetic products containing 1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one and not complying with those conditions shall not be made available on the Union market. ◀