Status: Point in time view as at 27/11/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1223/2009 of the European Parliament and of the Council, ANNEX V. (See end of Document for details)

### 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.
- [F12. 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 %]

#### **Textual Amendments**

**F1** Substituted by Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).

Referen	ceSubstan	ce identifi	cation		Conditio	ns		Wording
number	Chemica name/ INN	l 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
1	Benzoic acid and its sodium salt	Benzoic acid Sodium Benzoate	65-85-0 532-32-1	200-618-2 208-534-8	off products, except oral products	2,5 % (acid)		
					Leave- on products	(acid) 0,5 % (acid)		
1a	Salts of benzoic acid other than that listed under reference number 1 and	benzoate, calcium benzoate, potassium benzoate, magnesiu benzoate, MEA-	2090-05-2 582-25-2, 553-70-8, 14337-66-0 93-58-3, 193-89-0, 2315-68-0 136-60-7,	4217-468-5 3218-235-4 209-045-2 0224-387-2 202-259- 202-284-3 5219-020-8 205-252-204-401-3	4, 3, 2, 7, 3,	0,5 % (acid)		

	esters of benzoic acid	methyl benzoate, ethyl benzoate, propyl benzoate, butyl benzoate, isobutyl benzoate, isopropyl benzoate, phenyl benzoate	939-48-0, 93-99-2	213-361-6, 202-293-2			
2	Propionic acid and its salts	acid, ammonium propionat calcium	17496-08 n4075-81-4 e557-27-7, 327-62-8, e137-40-6 m e,	201-176-3, -241-503-7, 4223-795-8, 209-166-0, 206-323-5, 205-290-4	2 % (acid)		
3	Salicylic acid <sup>a</sup> and its salts	magnesiu	,59866-70 m54-21-7, ,578-36-9, ,2174-16-5	- <b>0</b> ,42-669-3, - <b>2</b> ,61-963-2,	0,5 % (acid)	Not to be used in products for children under 3 years of age, except for shampoos	Not to be used for children under 3 years of age <sup>b</sup>
4 4	Hexa-2,4- dienoic acid and its salts	Sorbic acid, calcium sorbate, sodium sorbate, potassium sorbate	7757-81-5 24634-61	203-768-7, 9231-321-6, 5231-819-3, - <b>2</b> 46-376-1	0,6 % (acid)		

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6	Moved or	deleted						· · · · · · · · · · · · · · · · · · ·
[ <sup>F10</sup> 7	Biphenyl- ol <sup>s</sup>	2)- Phenylph	90-43-7 enol	201-993-:	(a)	Rin)se- off Products	0,2 % (as phenol)	Avoid contact with eyes
					(b)	I(ta)ve- on products	0,15 % (as phenol)]	
8	Pyrithion zinc <sup>d</sup>	eZinc pyrithione		- <b>2</b> 36-671-3	Hair products	1,0 %	Only in rinse-off	
					Other products	0,5 %	products Not to be used in oral products	
9	Inorganic sulphites and hydrogen sulphites	sulfite, ammoniu bisulfite, ammoniu sulfite,	10192-30 ml0196-04 10117-38 m773-03-7 7631-90-3 16731-55	7231-821-4 -033-469-7 -033-484-9 -233-321-7231-870-5 5231-548-0 4231-673-0 -840-795-2	7, 9, 1, 1, 0,	0,2 % (as free SO <sub>2</sub> )		
10	Moved or	deleted						
11	Chlorobu	t <b>:Cilol</b> lorobu	<b>anol</b> 5-8	200-317-0	5	0,5 %	Not to be used in aerosol dispenser (sprays)	Contains Chlorobutano
[ <sup>F11</sup> 12	4- Hydroxylacid and its Methyl- and Ethyl- esters,	potassium ethylparal	36457-19 rall6782-08 15026-62-0 365285-68 120-47-8 114-63-6	202-804-9 202-785-7 -253-048-1 -240-830-2 0225-714-1 -252-487-0 204-399-4 204-051-1 -247-464-2	7 1 2 1 5 4	0,4 % (as acid) for single ester 0,8 % (as acid) for		

	and their salts	sodium methylparal sodium ethylparal sodium paraben potassium methylpar calcium paraben	pen pen	- <b>0</b> 74-235-4	1	mixtures of esters		
[F1212a	and its salts Propyl 4-	sodium	ablen 3-3 35285-69 ablen 57-20 38566-94 ben 30-16 i	- <b>8</b> 54-009-	7 1 7	0,14 % (as acid) for the sum of the individual concentra 0,8 % (as acid) for mixtures of substance mentioned in entry 12 and 12a, where the sum of the individual concentra of butyland propylpar and their salts does not exceed 0,14 %	application on the nappy area of children sunder dthree years of age.	For leave-on products designed for children under other of age: 'Do not use on the nappy area']
13	3- Acetyl-6- methylpy (3H)- dione and its salts	acid,	16807-48	224-580-	l *	0,6 % (as acid)	Not to be used in aerosol dispensers (sprays)	S
14	Formic acid and its	Formic acid,	64-18-6, 141-53-7	200-579- 205-488-0	l *	0,5 % (as acid)		

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	sodium salt	sodium formate					
15		4,sethionat ylenedioxy ine		<b>\$</b> 899-116-4		0,1 %	
16	Thiomers	aThimeros	a\$4-64-8	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	Phenylme salts (including borate)	Mercuric	62-38-4, 94-43-9	200-532-3 202-331-8		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
18	Undec-10 enoic acid and its salts	acid, potassium undecyler sodium	13398-33-2 1 <b>at&amp;</b> 22-14-1	7222-264-8 2215-331-8 1282-908-9 - <b>0</b> 60-247-7	3, 3, 9,	0,2 % (as acid)	

19	5- Pyrimidir 1,3- bis (2- ethylhexy	amine,	nate,	205-513-5	5	0,1 %		
20	hexahydr methyl-		30007-47	- <b>2</b> 50-001-	7Rinse-	0,1 %	Avoid	
20	Bromo-5-	Bromo-5- nitro-1,3- dioxane		200 001	off products	0,1 70	formation of nitrosami	
21	Bronopol	2- Bromo-2- nitropropa diol		200-143-0	)	0,1 %	Avoid formation of nitrosami	
22	2,4- Dichlorol alcohol		etr <i>īzīyī</i> l-82-8	3217-210-5	5	0,15 %		
23	1-(4- Chloroph (3,4- dichlorop urea <sup>f</sup>	enyl)-3-	odi01-20-2	202-924-		0,2 %	<1 ppm 3,3',4,4'-	roazobenzene roazoxybenzene
24	Chlorocre	spol Chloro- m- Cresol	59-50-7	200-431-0	to be used in products applied on mucuous membran	0,2 % es		
[ <sup>F13</sup> 25	5- Chloro-2- (2,4- dichlorop phenol		3380-34-5	5222-182-2	(a) Hand soaps Body soaps/ Shower gels	T(ac)thpaste	9,3 %	

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Chloro-xylenol   Chloroxy   288-04-0   201-793-8   0,5 %						` ′	S S	<b>n</b> ⊛%	]
N,N"- Imidazoli B92B6-46-254-372-6 methylene hixlaN '-[3- (hydroxymethyl)-2,5- dioxoimidazolidin-4-yl]urea]  Polyhexantuhydenie p22B9158-608-723-9 biguanide biguanide hydrochloride 27083-27-808-042-7 hydrochloride 28757-47-3, 133029-32-0  Phenoxyethaalee99-6 204-589-7 1,0 %	26		Chloroxy	l <b>&amp;</b> 8 <b>0</b> 04−0	201-793-8	3	0,5 %		
biguanide biguanide 27083-27-808-042-7 hydrochloride 28757-47-3, 133029-32-0  to be used in applications that may lead to exposure of the enduser's lungs by inhalation  29 2- Phenoxyethaae99-6 204-589-7 Phenoxyethanol 1,0 %	27	N,N"- methylene '-[3- (hydroxyn dioxoimic	ebiseaN nethyl)-2,5	5-	- <b>9</b> 54-372-6	5	0,6 %		
Phenoxyethanol	[ <sup>F1</sup> 28	biguanide	biguanide	27083-27 28757-47	- <b>8</b> 08-042-7 -3,		0,1 %	to be used in applicatio that may lead to exposure of the enduser's lungs by	ns
30 Methenam Methenam 1000-97-0 202-905-8 0,15 %	29		Phenoxye thanol	t <b>haa</b> e99-6	204-589-7	7	1,0 %		
	30	Methenan	n <b>Me</b> thenan	n <b>1:00</b> -97-0	202-905-8	3	0,15 %		

[F1432	1-(4- Clim Chlorophenoxy (imidazol-1- yl)-3,3- dimethylbutan- one <sup>t</sup>		- <b>9</b> 53-775-4	(b) (c) (d)	l <b>(b</b> i)ons" F( <b>a</b> ge	0,2 %" 0,2 %" 0,2 %" 0,5 %"	]
33	1,3-Bis DMI (hydroxymldyd) dimethylimidaz dione	alntoj <b>n</b> -	)229-222-8	3	shampoo <sup>u</sup> 0,6 %		
[F334	Benzyl Benz alcohol <sup>g</sup> Alco		202-859-9	)	1,0 %		]
35	methyl-6- meth (2,4,4- (2,4, trimethylp <b>trity</b> ) 2- 2- pyridon pyrid	roxy-468890-66- nyl-6- 4- Ethylpentyl) don, ctone	- <b>3</b> 72-574-2 -4	Rinse- off products Other products	1,0 %		
26	salt						
36 37	Moved or delet  2,2'- Bror methylenebis(6 bromo-4- chlorophenol)	noch draphan	- <b>2</b> 39-446-8	3	0,1 %		
38	4- o- Isopropyl-Cym m-cresol ol		2221-761-7	7	0,1 %		
[F1539	of 5- (and	nyliso <b>thazətia</b> d I)-	1220-239-6		0,0015 % (of a mixture in the ratio 3:1 of 5-chloro-2-methylise 3(2H)-one and 2-methylise (2H)-one)	thiazol	

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[F2	-							
F2]	-							
42	diimino-2 tetraazate and its	Chlorhexic Chlorhexic Mylac&thle, Chlorllexic Malghamadi Chlorhexic tDihydroch	<b>56.</b> 95-1, 18472-51 <b>56.</b> 97-42-5 temidine dine	-0,42-354-0	l, ),	0,3 % (as chlorhexid	dine)	
43	1- Phenoxyp ol <sup>h</sup>	Phenoxyise ropan-2-	ชีติถอติลัก <del>จ</del> ์ไ	212-222-7	Only for rinse-off products	1,0 %		
[F16[X144	Alkyl (C <sub>12-22</sub> ) trimethyl ammonius bromide and chloride	Behentrim chloride <sup>6</sup> , cetrimonium bromide, cetrimonium chloride <sup>7</sup> , laurtrimon bromide, laurtrimon chloride, steartrimon bromide, steartrimon chloride <sup>8</sup>	1017-09-0, 10112-02-7, 10112-00-5, 101120-02-1	200-311-3 203-928-6 214-290-3 203-927-6 214-294-5	3, 5, 3, ),	0,1 %		
45	4,4- Dimethyloxazolidii	Dimethyl -Q <b>3</b> azolidir ne		- <b>2</b> 57-048-2	2	0,1 %	pH > 6	
46	N- (Hydroxy N- (dihydrox dioxo-2,5 imidazolic N'- (hydroxy) urea	ymethyl-1,í - dinyl-4)-		- <b>2</b> 78-928-2	<u> </u>	0,5 %		
47	Benzenec 4,4'- (1,6- hexanediy	a <b>l·l·exaimiidla</b> Hexamidin diisethiona /lbis	<b>66</b> 59-40-5,	299-055-3		0,1 %		

	(oxy))bisand its salts (including isethionat and phydroxyb	e	ne					
48	Glutaraldo (Pentane- dial)		111-30-8	203-856-:	5	0,1 %	Not to be used in aerosols (sprays)	Contains glutaral <sup>i</sup>
49	5- Ethyl-3,7- dioxa-1- azabicycle [3.3.0] octane	7- Ethylbicy		5231-810-4 dine	1	0,3 %	Not to be used in oral products and in products applied on mucous membran	es
50	3-(p- Chloropho propane-1 diol	enoxy)-	n <b>&amp;Si4h</b> -29-0	203-192-0	5	0,3 %		
51	Sodium hydroxym acetate	Sodium Marxiyii		- <b>3</b> 74-357-8 inate	3	0,5 %		
52	Silver chloride deposited on titanium dioxide	Silver chloride	7783-90-6	5232-033-3		0,004 % (as AgCl)	20 % AgCl (w/w) on TiO <sub>2</sub> . Not to be used in products for children under 3 years of age, in oral products and in eye and lip products	

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53	N,N-dimethyl-N-[2-[2-[4-(1,1,3,3,-tetrameth ethyl]-, chloride	Chloride ylbutyl)ph	enoxy]etho		(b)	Runse off products Leave-on products other than oral products			_
54	chloride, bromide and	chloride, benzalkor bromide, abenzalkor	63449-41 1 <b>2:11:0</b> 80-29 68989-01 1 <b>6:84</b> 24-85 1 <b>6:8</b> 391-01	\$264-151-6 -293-522-5 -273-545-7 -270-325-7 -269-919-6 -287-089-7	5, 7, 2, <del>1</del> ,	0,1 % (as benzalkor chloride)	nium	Avoid contact with eyes	_
55	Methanol (phenylm		<b>ni4648:6</b> 0	- <b>2</b> 38-588-8	Rinse- off products	0,15 %			
56	3- Iodo-2- propynyll	Iodopropy butylcarba	amate	<b>-0</b> 59-627-5	(b) (c)	R(in)se- offb) p(w)ducts Leave- on products Deo- dorants/ anti- perspirants	ONO2t %6 One lus % d One lus % d One lus % d and lip products (a)	Not to be used in products fot) and children under 3 years of age, except in bath products/shower gels and shampoo Not to be used	Not to be used for children under 3 years of age Not to be used for children under 3 years of age sed for children under 3 years of age sed for age se

							(b) and (c)	in body lotion and body cream <sup>m</sup> Not to be used in products for children under 3 years of age	
[ <sup>F7</sup> 57	2- Methyl-2l isothiazol one	H- -3-		1 <u>2</u> 20-239-6	off products	0,0015 %		]	_
[ <sup>F4</sup> [ <sup>F17</sup> 58	Ethyl- N-alpha- dodecano L- arginate hydrochlo	yArginate HCl	60372-77	<b>-2</b> 34-630-6	(a)	<b>M</b> a)uthwas	A(245)5 %	Note to be used in preparation for children under 10 years of age	Not to be used for orshildren under 10 years of age
					(b)	Qtt)er products	Q( <b>b</b> )%	Not to be used in lip products, oral products (other than mouthwas	shes),

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							spray products]]
[ <sup>F5</sup> [ <sup>X1</sup> 59	Propanetr acid, 2- hydroxy-, monohyd and 1,2,3-	Silver r <b>æit</b> erate icarboxyli	460-890-3	5	0,2 %, correspon to 0,0024 % of silver	in oral products	]]
[F1860	ethoxy-4-	Hydroxye Butanone henyl)buta	99 <b>3</b> 3-435-8	3	0,7 %		1

- a For use other than as a preservative, see Annex III, No. 98.
- **b** Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin
- c [F2For use other than as a preservative, see Annex III, No. 13.]
- **d** For use other than as a preservative, see Annex III. No. 101.
- e For use other than as a preservative, see Annex III, No. 99.
- **f** For use other than as a preservative, see Annex III, No. 100.
- **g** [F3For other uses than preservatives, see Annex III, entry No 45.]
- **h** For use other than as a preservative, see Annex III, No. 54.
- i Only if the concentration exceeds 0,05 %.
- j For use other than as a preservative, see Annex III, No. 65.
- **k** Solely for products, other than bath products/shower gels and shampoo, which might be used for children under 3 years of age.
- l Solely for products which might be used for children under 3 years of age.
- m Concerns any products aimed to be applied on a large part of the body.
- **n** [F4For other uses than preservatives, see Annex III, entry No 197.]
- [F5]X1For use other than as a preservative, see Annex III, No 287.
- **p** For use other than as a preservative, see Annex III, No 286.]]
- **q** [F6Methylisothiazolinone 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.]
- r [F7Methylisothiazolinone 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.]
- § [F8From 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.]
- t [F9For use other than as a preservative, see Annex III, entry 310.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1223/2009 of the European Parliament and of the Council, ANNEX V. (See end of Document for details)

u 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.]

### **Editorial Information**

X1 Substituted by Corrigendum to Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products (Official Journal of the European Union L 238 of 9 August 2014).

#### **Textual Amendments**

- **F2** Deleted by Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F3** Substituted by Commission Regulation (EU) No 344/2013 of 4 April 2013 amending Annexes II, III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F4** Substituted by Commission Regulation (EU) 2016/1121 of 11 July 2016 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- F5 Inserted by Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products (Text with EEA relevance).
- **F6** Inserted by Commission Regulation (EU) No 1003/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- F7 Substituted by Commission Regulation (EU) 2017/1224 of 6 July 2017 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F8** Inserted by Commission Regulation (EU) 2018/1847 of 26 November 2018 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F9** Inserted by Commission Regulation (EU) 2019/698 of 30 April 2019 amending Annexes III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F10** Substituted by Commission Regulation (EU) 2018/1847 of 26 November 2018 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F11** Substituted by Commission Regulation (EU) No 1004/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F12** Inserted by Commission Regulation (EU) No 1004/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F13** Substituted by Commission Regulation (EU) No 358/2014 of 9 April 2014 amending Annexes II and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F14** Substituted by Commission Regulation (EU) 2019/698 of 30 April 2019 amending Annexes III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).

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- **F15** Substituted by Commission Regulation (EU) No 1003/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F16** Substituted by Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products (Text with EEA relevance).
- **F17** Inserted by Commission Regulation (EU) No 344/2013 of 4 April 2013 amending Annexes II, III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).
- **F18** Inserted by Commission Regulation (EU) 2019/1858 of 6 November 2019 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance).

### **Status:**

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# **Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EC) No 1223/2009 of the European Parliament and of the Council, ANNEX V.