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**GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS**

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**DEPARTMENT OF HEALTH****NO. 921****19 AUGUST 2016****FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972  
(ACT NO. 54 OF 1972)****REGULATIONS RELATING TO THE LABELLING, ADVERTISING AND  
COMPOSITION OF COSMETICS**

The Minister of Health intends, in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), as amended, to make the regulations in the Schedule.

Interested persons are invited to submit, within three months of publication of this notice, comments or representations on the proposed regulations to the Department of Health, for the attention of the Registrar: Medicines Control Council, Private Bag X828, Pretoria, 0001.

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## DEFINITIONS

1. In these regulations any word or expression to which a meaning has been assigned in the Act has that meaning, and unless the context otherwise indicates-

**"Act"** means the Foodstuffs, Cosmetic and Disinfectants Act, 1972 (Act No. 54 of 1972);

**"address"** means an address in the Republic of South Africa giving the street or road number (if a number has been allotted), the name of the street or road and the name of the town, village or suburb and, in the case of imported cosmetics, "address" means the address of the importer or distributor in the Republic;

**"Annex"** means an Annex to these regulations;

**"batch number" or "lot number"** means a unique number or combination of numbers or ciphers allocated to a batch or a lot, respectively, by the manufacturer;

**"bulk stock container"** means a container that contains more than one unit of any specific cosmetic product;

**"claim"** means any written, pictorial, visual or other descriptive matter or any verbal statement, communication, representation or reference which is brought to the attention of the public in any manner, including a trade name or brand name, and which refers to the characteristics of a product, in particular to its nature, identity, properties, composition, quality, durability, origin or method of manufacture or production;

**"colourant"** means any substance referred to in Annex IV which is exclusively or mainly intended to colour the cosmetic, the body as a whole or certain parts thereof, by absorption or reflection of visible light;

**"date of minimum durability"** means the date until which the cosmetic, stored under appropriate conditions, will continue to fulfil its initial function;

**"distributor"** means any person in the supply chain, other than the manufacturer or importer, who makes a cosmetic available on the market;

**"GMP"** means Good Manufacturing Practice;

**"INCI"** means the International Nomenclature for Cosmetic Ingredients;

**"ingredient"** means any substance, including any cosmetic additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a cosmetic and which remains in the final product;

**"indelible"** means the information on the label should be legible throughout the period for which the product is used;

**"ISO"** means International Organisation for Standardization;

**"legible"** means that the labelling should be of sufficient size so that the details can be read by a person with normal vision at a distance of about 30 cm or by a person

wearing normal corrective lenses without having to resort to aids such as magnification;

**"letter"** includes a digit;

**"manufacturer"** means any person who manufactures a cosmetic or has such a product designed or manufactured under his or her name or trademark and markets that cosmetic;

**"name of the cosmetic"** means a word or words which give a true description of the cosmetic and which can distinguish such cosmetic from other products it could be confused with;

**"nominal content"** means the quantity indicated on the label of the cosmetic;

**"preservative"** means any substance referred to in Annex VI which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic and protects it against spoilage;

**"pressurised container"** means a container of metal, glass or plastic or a composition of these materials which contains liquids, powders or semisolids and a propellant and which discharges its contents under pressure through a valve system;

**"primary container"** means a container which is in direct contact with the cosmetic;

**"SANS"** means the South African National Standards;

**"secondary container"** means a container which is not in direct contact with the cosmetic;

**"UV Filter"** means any substance referred to Annex VII which is exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation

**"visible"** means that the information on the label should not be obscured and should be seen without having to break open any component of packaging;

**Category of Cosmetics**

2. A non exhaustive, non exclusive, illustrative list by category of cosmetic is listed in Annex I.

**Safety**

3. (1) No person may sell, manufacture or import for sale, any cosmetic that may cause damage to human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular-

- (a) product presentation;
- (b) labelling;
- (c) instructions for use and disposal; and
- (d) any other indication or information provided by the manufacturer, packer, distributor, importer or person on whose behalf the cosmetic is packed.

- (2) The manufacturer or distributor must appoint a suitably trained person to perform an assessment of the safety for human health of the finished product and its ingredients.

**Product Information File**

4. (1) When a cosmetic is marketed, the manufacturer, packer, distributor, importer or person on whose behalf the cosmetic is packed must, prior to placing a product on the South African market and for control purposes, keep a product information file for each cosmetic.

- (2) The product information file must contain at least the following information and data which must be updated as necessary:

- (a) A description of the cosmetic.
- (b) A qualitative and quantitative composition of the cosmetic.
- (c) Physical, chemical and microbiological specifications of the raw materials and the finished product.

- (d) A description of the methods of manufacture complying with Good Manufacturing Practice.
- (e) An assessment for the safety of human health of the finished product resulting from the use of the cosmetic product and the details of the responsible assessor.
- (f) Where justified by the nature or the effect of the cosmetic, scientific substantiation of the effect claimed for the cosmetic.

(3) The manufacturer, packer, importer, distributor or person on whose behalf the cosmetic is packed must make the product information file readily accessible in electronic or other format at the address indicated on the cosmetic label.

(4) Unless expressly otherwise provided in the regulations published in terms of the Act, the information required to appear in the product information file must be in English.

#### **Good Manufacturing Practice**

5. (1) The manufacture of cosmetics must comply with GMP.

(2) Compliance with GMP is presumed where the manufacture of a cosmetic is in accordance with standard 22716 of the ISO and standard 22716 of the SANS.

#### **Product Composition**

6. (1) For the purposes of section 3(1) (a) (i), (ii) and (iii) of the Act, no person may sell or manufacture or import or distribute for sale any cosmetic containing-

- (a) a prohibited substance listed in Column 2 of Annex II;
- (b) a restricted substance listed in Column 2 of Annex III Part I, Annex III Part 2 and Annex III Part 3; unless the corresponding restrictions, conditions of use and warnings to be printed on the label, as specified in Columns 3, 4, 5 and 6 of the said Annex, are complied with;
- (c) a colourant other than those listed in Column 1 and 2 of Annex IV;
- (d) a colourant listed in Column 1 and 2 of Annex IV but not used in accordance with the field of application referred to in Columns 3, 4,

- 5 and 6 and limitations and subject to any limitations and requirements referred to in Column 7 of the said Annex;
- (e) a substance referred to in Annex V, unless listed as an exception and referred to in another Annex;
  - (f) a preservative other than those listed in Column 2 of Annex VI;
  - (g) a preservative listed in Column 2 of Annex VI but not used in accordance with the restrictions and warnings to be printed on the label as referred to in Columns 3, 4 and 5;
  - (h) a UV Filter other than those listed in Column 3 of Annex VII;
  - (i) a preservative listed in Column 3 of Annex VII but not used in accordance with the restrictions and warnings to be printed on the label as referred to in Columns 4, 5 and 6;

(2) For the purposes of section 3(1) (a) (i), (ii) and (iii) of the Act, no person may sell or manufacture or import or distribute for sale any cosmetic that does not carry warning statements as listed in the relevant Annexes.

### **Labelling**

7. (1) Save as provided in sub-regulation (2), the immediate container of every cosmetic for sale in the Republic of South Africa must have a label attached to it on which at least the following particulars must appear in indelible, easily legible and visible lettering in at least English:

- (a) The name of the cosmetic.
- (b) The name of the manufacturer, packer, importer, distributor or person on whose behalf the cosmetic is packed.
- (c) The business address of the manufacturer, packer, importer, distributor or person on whose behalf the cosmetic is packed: Provided that where it is not physically possible to provide this information on the primary container, such information must appear on the secondary container.
- (d) The country of origin for imported cosmetics.
- (e) The nominal content at the time of packaging given by weight or volume.
- (f) The date of minimum durability (where necessary).

- (g) The particular precautions and warning statements to be observed in use, where applicable, and at least those listed in Annexes II, III, IV, VII and VII.
  - (h) The batch number or lot number of the cosmetic.
  - (i) The list of ingredients according to INCI nomenclature and must be preceded by the term "ingredients": Provided that where this is impossible for practical reasons because the cosmetics are too small, such information need only appear on the secondary container.
  - (j) The function of the cosmetic, unless it is clear from its presentation.
- (2) If a cosmetic bears both a primary container label and a secondary container label, the requirements of sub-regulation (1) apply to the secondary container label as well.
- (3) Where it is impossible for practical reasons to label a cosmetic with information mentioned in sub-regulation (1), the information must be-
- (a) mentioned on an attached leaflet, label, inlay, tape, tag or card;
  - (b) unless impracticable, referred to by abbreviated information or the symbol given in point 1 of Annex VII, which must appear on the primary container for the information referred to in sub-regulation (1)(g) and on the secondary container for the information referred to in sub-regulation (1)(i).
- (4) In the case of soap, bath balls and other small products, where it is impossible for practical reasons for the information referred to in sub-regulation (1)(i), to appear on a leaflet, label, inlay, tape, tag or card, the information must appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.
- (5) Cosmetics are exempt from nominal content marking, as contemplated in sub-regulation (1)(e), if they are-
- (a) free samples;
  - (b) packs containing less than five grams or five millilitres;
  - (c) single application packs such as sachets; or

- (d) pre-packages normally sold as a number of items, for which the details of weight or volume are not significant: Provided the number of items appears on the packaging e.g. bath balls but this number need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually.
- (6) The date of minimum durability, as contemplated in sub-regulation (1)(f), must be clearly expressed and may consist of either the month and year or the date, month and year.
- (7) An indication of the date of minimum durability as contemplated in sub-regulation (1)(f), is not mandatory for cosmetics with a minimum durability of more than 30 months: Provided that for such cosmetics, there is an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer and this information is indicated by the symbol shown in Annex IX followed by the period of time.
- (8) The label of a cosmetic in any pressurised container must contain a warning statement indicating that the container-
  - (a) is pressurised;
  - (b) should be protected from direct sunlight and not be exposed to temperatures exceeding 50 °C; and
  - (c) should not be pierced, punctured, burnt or incinerated, even after use.
- (9) The names used for ingredients on a label must correspond with those used in the Annexes or in INCI nomenclature and must correspond to those names used in the International Cosmetics Ingredients Dictionary: Provided that if an ingredient is not described in the aforementioned publication, the description thereof in the United States Pharmacopoeia, the British Pharmacopoeia or the European Pharmacopoeia may be used.
- (10) In the list of ingredients as contemplated in sub-regulation (1)(i)-
  - (a) perfume and aromatic compositions and their raw materials must be referred to by the terms "parfum" or "aroma";
  - (b) these must be listed in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in

- concentrations of less than one percent may be listed in any order after those concentrations of more than one percent;
  - (c) colourants other than colourants intended to colour hair may be listed in any order after the other cosmetic ingredients, in accordance with the colour index number referred to in Annex IV;
  - (d) for decorative cosmetic products marketed in several shades, all colouring agents used in the range may be listed, provided that the words 'may contain' or the symbol '+/-' are added.
- (11) The following are not regarded as ingredients:
- (a) Impurities in the raw materials used.
  - (b) Subsidiary technical materials used in the mixture but not present in the final product.
- (12) Unless expressly otherwise provided in regulations made in terms of the Act, the information required to appear on a label must be in at least one of the official languages of the Republic of South Africa.
- (13) Information required to appear on a label must be visible, legible and indelible and the legibility thereof must not be obstructed by pictorial or any other matter, printed or otherwise.
- (14) Prohibited product claims are not allowed on the label of the cosmetic.
- (15) Where an unlabelled cosmetic is sold from a bulk stock container, such bulk stock container must be labelled in accordance with the requirements of sub-regulation (1), and the label must state the special storage conditions where applicable.

### **Product Claims**

8. (1) In the labelling, making available on the market and advertising of a cosmetic, text, names, trademarks, pictures and figurative or other signs are not used to imply that these products have characteristics or functions which they do not have.

(2) The manufacturer, packer, distributor, importer or person on whose behalf the cosmetic is packed, must refrain from making any claims in respect of the cosmetic, its nature, effects and quality that cannot be scientifically substantiated and must refrain from using the words 'clinically proven' unless scientifically substantiated.

(3) Any person selling any cosmetic bearing a label with the words "recommended by doctors" or any other word or words or pictorial representation implying that medical practitioners in general recommend its use, is guilty of an offence.

(4) Any person selling any cosmetic bearing on a label any word, indication or claim that conveys the impression that the cosmetic possesses health-giving properties is, unless such word, indication or claim can be scientifically substantiated, be guilty of an offence.

(5) The manufacturer, packer, distributor, importer or person on whose behalf the cosmetic is packed may refer, on the secondary container of the cosmetic or in any notice, document, label accompanying or referring to the cosmetic product, to the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished cosmetic product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetics.

### **Advertising**

9. No person may advertise a cosmetic in an advertisement which contains any information, claim, reference or performance explanation which is not allowed on the label of a cosmetic in terms of these regulations.

### **Penalties**

10. (1) Any person convicted of an offence under, or failure to comply with these regulations, is liable -


- (a) on a first conviction, to a fine or to imprisonment for a period not exceeding six months or to both a fine and such imprisonment;
- (b) on a second conviction, to a fine or to imprisonment for a period not exceeding twelve months or to both a fine and such imprisonment;
- (c) on a third or subsequent conviction, to a fine or to imprisonment for a period not exceeding twenty-four months or to both a fine and such imprisonment.

### **Repeals**

11. Government Notice No. R. 908 of 27 May 1977, as amended by Government Notices Nos R. 1389 of 22 July 1977, R. 1843 of 28 August 1981, R. 2298 of 26 October 1984 and R.2567 of 15 November 1985, and Government Notice No. R. 1227 of 24 June 1988, as amended by Government Notices Nos. R. 1783 of 2 September 1988 and R. 1861 of 10 August 1990, are hereby repealed in so far as they relate to cosmetics.

### **Short title and commencement**

12. These regulations are called the Regulations Relating to the Labelling, Advertising and Composition of Cosmetics, 2016.



**DR A MOTSOLEDI, MP**  
**MINISTER OF HEALTH**  
**DATE:** 30/5/2016

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## ANNEX I

### ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

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- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc)
- Face masks (with the exception of chemical peeling products)
- Anti-wrinkle products
- Tinted bases (liquids, pastes, powders)
- Toilet soaps, deodorant soaps, etc
- Bath and shower preparations (salts, foams, oils, gels, etc)
- Perfumes, toilet waters and eau de Cologne
- Deodorants and anti-perspirants
- Depilatories
- Shaving products (creams, foams, lotions, etc)
- Hair care products:
  - ⇒ Hair tints and bleaches
  - ⇒ Products for waving, straightening and fixing
  - ⇒ Setting products
  - ⇒ Cleansing products (lotions, powders, shampoos)
  - ⇒ Conditioning products (lotions, creams, oils)
  - ⇒ Hairdressing products (lotions, lacquers, brilliantine's)
- Make-up powders, after bath-powders, hygienic powders, etc
- Products for nail care and make-up
- Products for making-up and removing make-up from the face and the eyes
- Products intended for application to the lips
- Products for care of the teeth and the mouth
- Products for external intimate hygiene
- Sunbathing products
- Products for tanning without the sun
- Skin-whitening products

## **ANNEX II**

### **LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS**

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The alphabetical list set out in column 2 of this Annex contains one or more of the names of each of the substances not allowed in cosmetic products. In certain cases a name is given for a group of substances, the names of particular examples of which are also given, and in such a case all substances comprised in the group are included, whether or not more specifically named.

The numbers given in columns 1, 3 and 4 are for information only.

Those in column 3 are cross-references to other names listed for the same substances (except where a name is that of a group of substances, the cross-references are to particular examples of that group, and any cross-reference in parenthesis is to the name of a group of substances within which the particular substance falls).

Those in column 4 are cross-references to Annex II of the original EU Directive, from which this Annex is derived.

## ANNEX II

LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF  
THE COMPOSITION OF COSMETIC PRODUCTS

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
1	Acenocoumarol (INN)	397	254
2	Acetonitrile	-	393
3	3-( <i>a</i> -Acetonylbenzyl)-4-hydrocoumarin and its salts	399, 761	203
4	b-Acetoxyethyl trimethyl ammonium hydroxide (acetylcholine and its salts)	6	2
5	2-Acetylamino-5-chlorobenzoxazole	165	1
5a	3-[(4-(Acetylamino)phenyl)azo]-4-hydroxy-7-7[[[5-hydroxy-6-(phenylazo)-7-sulfo-2-naphthalenyl]amino]carbonyl]amino]-2-naphthalenesulfonic acid and its salts, when used as a substance in hair dye products		1269
6	Acetylcholine and its salts	4	2
7	Acetylene chlorides	250, 758	126
8	Acetylenic alcohols, their esters, ethers and salts	17	16
9	Acetyl ethyl tetramethyl tetralin (AETT)	342, 698a	362
10	7a-Acetylthio-3-oxopregn-4-ene-17a, 17propionolactone	650	4
10a	Acid Black 131 (CAS No 12219-01-1) and its salts, when used as a substance in hair dye products		1252
11	Aconitine (principal alkaloid of <i>Aconitum napellus</i> L.) and its salts	-	12
12	<i>Aconitum napellus</i> L. leaves, roots and galenical preparations	-	11
13	<i>Adonis vernalis</i> L. and its preparations	-	13
14	Adrenaline	270, 315	14
14a	Alanroot oil ( <i>Inula helenium</i> ) (CAS No. 97676-35-2) when used as a fragrance ingredient	-	423
15	Alkali pentacyanonitrosylferrate(2-)	603, 645	255
16	<i>o</i> -Alkyldithiocarbonic acids, salts of	762	336
17	Alkyne alcohols, their esters, ethers and salts	8	16

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
18	Alloclamide (INN) and its salts	22	19
19	Allyl isothiocyanate	-	18
20	2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts	-	224
21	N-Allylnormorphine, its salts and ethers	493	20
22	2-Allyloxy-4-chloro-N-[2-(diethylamino)-ethyl] benzamide and its salts	18	19
23	Alypine and its salts	45, 110	143
24	Amibenonium chloride (INN)	(528)	132
24a	4-Aminobenzenesulfonic acid (CAS No 121-57-3) and its salts, when used as a substance in hair dye products		1257
25	4-aminobenzoic acid and its esters, with the free amino group		167
26	2-Amino-1,2-bis(4-methoxyphenyl) ethanol and its salts	-	29
27	Aminocaproic acid (INN) and its salts	31	7
28	2-Amino-5-chlorobenzoxazole	768	24
29	4-Amino-N-(2-diethylaminoethyl)benzamide, its salts and derivatives	608	25
29a	5-Amino-4-Fluoro-2-Methylphenol Sulfate, when used as a substance in hair dye products.		1222
29b	4-amino-3-fluorophenol	53	1242
29c	5-Amino-2,6-Dimethoxy-3-Hydroxypyridine (CAS No 104333-03-1) and its salts, when used as a substance in hair dye products		1308
29d	1-Amino-4-[[4-[(dimethylamino)methyl]phenyl]amino]anthraquinone (CAS 12217-43-5 and its salts, when used as a substance in hair dye products		1278
29e	6-Amino-2-(2,4-dimethylphenyl)-1H-benz[de]isoquinoline-1,3(2H)- dione (CAS No 2478-20-8) (Solvent Yellow 44) and its salts, when used as a substance in hair dye products.		1277
30	Aminoheptane, its isomers and salts	749	27
30a	3(or5)-[[4-[(7-amino-1-hydroxy-3-sulphonato-2-naphthyl)azo]-1- naphthyl]azo]salicylic acid and its salts, when used as a substance in hair dye products		1266

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
31	6-Aminohexanoic acid and its salts	27	7
31a	1-Amino-4-(methylamino)-9,10-anthracenedione (CAS No 1220-94-6) (Disperse Violet 4) and its salts, when used as a substance in hair dye products.		1283
32	a-(Aminomethyl)-3,4-dihydroxybenzyl alcohol and its salts	518	257
33	4-Amino-N10-methylfolic acid	453	6
33a	2-Aminomethyl-p-aminophenol and its HCl salt, when used as a substance in hair dye products		1230
34	2-Amino-6-methylheptane and its salts	288, 524	28
35	2-Amino-4-methylhexane and its salts	289, 472	30
35a	2-Amino-3-nitrophenol (CAS No 603-85-0) and its salts, when used as a substance in hair dye products		1317
36	2-Amino-4-nitrophenol	-	383
37	2-Amino-5-nitrophenol	-	384
38	4-Amino-2-nitrophenol	-	412
38a	(8-[(4-Amino-2-nitrophenyl)azo]-7-hydroxy-naphthyl)trimethyl ammonium and its salts, except Basic Red 118 (CAS 71134-97-9) as impurity in Basic Brown 17), when used as a substance in hair dye products.		1291
38b	6-Amino-o-cresol (CAS No 17672-22-9) and its salts, when used as a substance in hair dye products		1315
38c	1-[(3-Aminopropyl)amino]-4-(methylamino)anthraquinone and its salts, when used as a substance in hair dye products		1303
38d	4-[(4-Aminophenyl)(4-iminocyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine (CAS 3248-93-9; EINECS 221-832-2) and its hydrochloride salt (Basic Violet 14; CI 42510) (CAS 632-99-5; EINECS 211-189-6) when used as a substance in hair dye products		1329
39	4-Aminosalicylic acid and its salts	-	31
40	Aminotoluenes, their isomers, salts and halogenated and sulphonated derivatives	717	32
41	Aminoxylenes, their isomers, salts and halogenated and sulphonated derivatives	764	33

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
42	Amitriptyline (INN) and its salts	284	146
43	<i>Ammi majus</i> and its galenical preparations	-	35
44	Amphetamine (INN), its salts and derivatives and salts of those derivatives	(679)	21
45	Amydracaine and its salts	23, 110	143
46	Amylene chloride	251	36
47	Amyl 4-dimethylaminobenzoate, mixed isomers	533	381
48	Amyl nitrites	-	247
49	Amylobarbitone and its salts	(70)	220
50	Amylocaine and its salts	282	50
51	<i>Anamirta cocculus</i> L. (fruit)	-	106
52	Substances with androgenic effect	-	37
53	Aniline, its salts and halogenated and sulphonated derivatives	-	22
53a	9,10-Anthracenedione, 1-[(2-hydroxyethyl)amino]-4-(methylamino)- (CAS No 86722-66-9) and its derivatives and salts, when used as a substance in hair dye products		1300
53b	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene] cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Blue 26; CI 44045) (CAS 2580-56-5; EINECS 219-943-6) when used as a substance in hair dye products		1340
54	Anthracene oil	-	38
55	Anti-androgens with steroid structure	-	390
56	Antibiotics	-	39
57	Antimony and its compounds	-	40
58	<i>Apocynum cannabinum</i> L. and its preparations	-	41
59	Apomorphine and its salts	695	42
60	Apronalide	420	216
61	Arecoline	483	238
62	Aristolochic acid and its salts; <i>Aristolochia</i> spp. and their preparations	-	365

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
63	Arsenic and its compounds	-	43
64	(Omitted)		
65	<i>Atropa belladonna</i> L. and its preparations	-	44
66	Atropine, its salts and derivatives	-	45
67	Azacyclonol (INN) and its salts	305	286
68	Azamethonium bromide (INN)	(474)	121
69	Barbitone and its salts	(70)	220
70	Barbiturates	546, 557, 630, 640, 707	220
71	Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, and lakes, salts and pigments prepared from the colouring agents listed with the reference (3) in Annex IV.	-	46
72	Bemegride (INN) and its salts	337, 338	183
73	Benactyzine (INN)	258	157
74	Bendrofluazide and its derivatives	75, 91	53
75	Bendroflumethiazide (INN) and its derivatives	74, 91	53
75a	Benzadiazepines	78	49
76	Benzamine and its salts	742	51
77	Benzatropine (INN) and its salts	301	158
78	Benzazepines, their salts and derivatives	75a	49
78a	Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-2-methyl phenyl]azo]-N,N,N-trimethyl-and its salts, when used as a substance in hair dye products		1297
78b	Benzenaminium, 3-[[4-[[diamino(phenylazo)phenyl]azo]-1-naphthalenyl]azo]-N,N,N-trimethyl-and its salts, when used as a substance in hair dye products		1298
79	Benzene	-	47
79a	1,3-Benzenediamine, 4-methyl-6-(phenylazo)-and its salts, when used as a substance in hair dye products.		1294
80	Benzene-1,2-diol	154, 628	408

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
80a	Benzenesulfonic acid, 5-[(2,4-dinitrophenyl)amino]-2-(phenylamino)- (CAS No 15347-52-1) and its salts, when used as a substance in hair dye products		1280
80b	1,2,4-Benzenetriacetate (CAS No 613-03-6) and its salts, when used as a substance in hair dye products		1254
80c	Benzenemethanaminium, N-ethyl-N-(4-((4-ethyl((3-sulfophenyl) amino)phenyl)(4-hydroxy-2-sulfophenyl)methylene)-2,5- cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt (Fast Green FCF; CI 42053) (CAS 2353-45-9; EINECS 219-091-5) when used as a substance in hair dye products		1357
81	Benzene-1,2,3-triol	629	409
82	(Omitted)		
83	2-Benzhydryloxyethyl dimethylamine and its salts	296	339
84	Benzidine	243	26
85	Benzilium bromide (INN)	96	60
86	2-Benziloyloxymethyl-1,1-dimethylpyrrolidinium methyl sulphate	600	239
87	Benzimidazolone	88, 267	48
88	Benzimidazol-2(3H)-one	87, 267	48
89	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol, except for normal content in natural essences used.	212	357
90	Benzo[a]phenoxazin-7-ium, 9-(dimethylamino)-, and its salts, when used as a substance in hair dye products.		1276
91	Benzothiadiazine and its derivatives	74, 75	53
91a	Benzothiazolium, 2-[[4-ethyl(2-hydroxyethyl)amino]phenyl]azo]- 6-methoxy-3-methyl- and its salts when used as a substance in hair dye products		1261
92a	Benzyl cyanide (CAS No. 140-29-4), when used as a fragrance ingredient	-	424
93	(Omitted)		
94	3-(N-Benzylhydrazinocarbonyl)-5-methylisoxazole	415	52

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
95	Benzylideneacetone	565	356
95a	3(or5)-((4-(Benzylmethylamino)phenyl)azo)-1,2-(or 1,4)-dimethyl-1H-1,2,4-triazolium and its salts, when used as a substance in hair dye products		1259
96	3-Benzoyloxy-1,1-diethylpyrrolidine hydrobromide	85	60
97	4-Benzoyloxyphenol	(323), 459	178
98	2-[Benzyl-N-(2-pyridyl)amino]-ethyl dimethylamine	624, 746	347
99	Bergapten(e) (except natural content of essences) In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg	(357)	358
100	Beryllium and its compounds	-	54
101	Betamethasone (INN)	(361)	300
102	Betoxycaine (INN) and its salts	257	23
103	BHC (ISO) ( <i>gamma</i> -BHC)	429, 370, 372	195
104	Bietamiverine (INN)	261	287
105	1,6-Bis(2-chloroethylamino)-1,6-dideoxy-mannitol and its salts	437	89
106	2-[Bis(2-chloroethyl)amino]-1-oxa-3-aza-2-phosphacyclohexane-2-oxide and its salts	109, 231	88
107	<i>N,N</i> -Bis(2-chloroethyl)methylamine and its salts	161, 491	87
108	<i>N,N</i> -Bis(2-chloroethyl)methylamine- <i>N</i> -oxide and its salts	492	86
109	<i>N,N</i> -Bis(2-chloroethyl)-1,3,2-oxaza-phosphinan-2-ylamine-P-oxide and its salts	106, 231	88
110	1,1-Bis(dimethylaminomethyl)propyl benzoate and its salts	23, 45	143
110a	bis(2-Ethylhexyl) phthalate CAS No 117-81-7		677
111	Bis(hydroxyalkyl)amines, not further <i>N</i> -substituted	255, 274, 641	411
111a	2,6-Bis(2-Hydroxyethoxy)-3,5-Pyridinediamine and its HCl salt, when used as a substance in hair dye products		1215
111b	4,6-Bis(2-Hydroxyethoxy)- <i>m</i> -Phenylenediamine and its salts, when used as a substance in hair dye products		1307
112	2,2-Bis(hydroxymethyl)butan-1-ol trinitrate	614	206

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
113	2,6-Bis(β-hydroxyphenethyl)-1-methylpiperidine and its salts	431	219
114	3,3-Bis(4-hydroxyphenyl)phthalide	558	417
115	Bis(8-hydroxyquinolinium)sulphate, except for the uses provided for in entry number 51 in Annex III, Part 1.	(401, 532)	395
115a	bis(2-Methoxyethyl)phthalate CAS No 117-82-8		678
115b	1,4-bis(p-Tolylamino)anthraquinone (Solvent Green 3; CI 61565) (CAS 128-80-3; EINECS 204-909-5 when used as a substance in hair dye products		1364
116	Bithionol (INN)	706	352
117	Bretylium tosylate (INN) (Bretylium tosylate)	120	56
118	Bromine, elemental	-	55
119	Bromisoval (INN)	122	58
120	<i>p</i> -Bromobenzylethyldimethylammonium <i>p</i> -toluenesulphonate	117	56
121	2-Bromo-2-ethylbutylurea	150	57
122	2-Bromo-3-methylbutylurea	119	58
123	1- <i>p</i> -Bromophenyl-1-(2-pyridyl)-3-dimethylaminopropane and its salts	124	59
124	Brompheniramine (INN) and its salts	123	59
125	Brucine	-	62
126	Butanilcaine (INN) and its salts	467	90
127	Butobarbitone and its salts	(70)	220
128	Butopirine (INN) and its salts	130	288
129	2-Butoxy- <i>N</i> -(2-diethylaminoethyl)-cinchoninamide and its salts	192	129
130	2-Butoxyethyl phenyl(piperidino)acetate and its salts	128	288
131	1-Butyl-3-( <i>N</i> -crotonoylsulphanilyl) urea	-	108
132	4-Butyl-1,2-diphenylpyrazolidine-3,5-dione	564	67
133	4- <i>tert</i> -Butyl-3-methoxy-2,6-dinitrotoluene	490	414
134	4-Butyl-1-phenylpyrazolidine-3,5-dione	487	64
135	1-Butyl-3-( <i>p</i> -methylbenzenesulphonyl)urea	716	65

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
136	1-Butyl-3-sulphanilylurea	151	66
137	4-Butylthiobenzhydriyl 2-(dimethylamino) ethyl sulphide	144	140
137a	5- <i>tert</i> -Butyl-1,2,3-trimethyl-4,6-dinitrobenzene		422
138	Cadmium and its compounds	-	68
139	Calabar bean	586	281
140	Calciferol	317, (760)	335
140a	Calcium 3-Hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate (Pigment Red 63:1; CI 15880) (CAS 6417-83-0; EINECS 229-142-3) when used as a substance in hair dye products		1349
141	Cantharides, <i>Cantharis vesicatoria</i>	648	69
142	Cantharidin	379	70
143	Captan (ISO)	735	370
144	Captodiamine (INN)	137	140
145	Caramiphen (INN) and its salts	568	169
146	<i>N</i> -(3-Carbamoyl-3,3-diphenylpropyl)- <i>N,N</i> -diisopropylmethyl ammonium salts	419	156
147	Carbazole, nitroderivatives of	509	72
148	Carbon disulphide	-	73
149	Carbon tetrachloride	691	315
150	Carbromal (INN)	121	57
151	Carbutamide (INN)	136	66
152	Carisoprodol (INN)	481	235
153	Catalase	-	74
154	Catechol	80, 628	408
155	Cells, tissues or products of human origin	-	416
156	Cephaeline and its salts	-	75
157	<i>Chenopodium ambrosioides</i> (essential oil)	-	76
158	Cherry laurel water	619	291

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
159	Choral hydrate	733	77
160	Chlorine	-	78
161	Chlormethine (INN) and its salts	107, 491	87
161a	4-Chloro-2-Aminophenol, when used as a substance in hair dye products		1219
162	Chloromezanone (INN)	176	91
163	4-Chlorobenzene-1,3-disulfonamide	195	85
164	5-Chloro-1,3-benzoxazol-2(3H)-one	187	82
165	N-5-Chlorobenzoxazol-2-ylacetamide	5	1
165a	2,2'-((3-Chloro-4-((2,6-dichloro-4-nitrophenyl)azo)phenyl)imino)bisethanol(CAS 23355-64-8)(Disperse Brown 1) and its salts when used as a substance in hair dye products		1260
165b	N-[6-[(2-Chloro-4-hydroxyphenyl)imino]-4-methoxy-3-oxo-1,4-cyclohexadien-1-yl]acetamide (CAS No 66612-11-1) (HC Yellow No 8 and its salts, when used as a substance in hair dye products		1304
165c	[6-[[3-Chloro-4-(methylamino)phenyl]imino-4-methyl-3-oxocyclohexa-1,4-dien-1-yl]urea (CAS No 56330-88-2) (HC Red No 9) and its salts, when used as a substance in hair dye products		1305
165d	6-Chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one (VAT Red 1; CI 73360) (CAS 2379-74-0; EINECS 219-163-6) when used as a substance in hair dye products		1365
165e	N-(5-Chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide(Pigment Red 5; CI 12490) (CAS 6410-41-9; EINECS 229-107-2) and its salts when used as a substance in hair dye products		1347
166	2-Chloro-6-methylpyrimidin-4-yl dimethylamine	170, 217	83
167	2-Chloro-9-[-3-dimethylamino]propylidene]thioxanthene ( <i>cis</i> -form) and its salts	184	84
168	Chloroethane	328	96
169	Chloroform	734	366

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
170	2-Chloro-6-methylpyrimidin-4-ylidene thylamine	166, 217	83
170a	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine (CAS No 50610-28-1) and its salts, when used as a substance in hair dye products		1318
170b	2-[(4-Chloro-2-nitrophenyl)amino]ethanol (CAS No 59320-13-7) (HC Yellow No 12) and its salts, when used as a substance in hair dye products		1325
170c	2-[(4-Chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutanamide (CAS 13515-40-7) (Pigment Yellow 73) and its salts, when used as a substance in hair dye products		1262
170d	1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085) (CAS 2814-77-9; EINECS 220-562-2) and its salts when used as a substance in hair dye products		1345
171	Chlorophacinone (ISO)	177	93
172	1-(p-Chloro-a-phenylbenzyl)-4-(2-hydroxyethoxyethyl)piperazine	402	240
173	2-(4-Chlorophenyl)-1-[4-(2-diethylaminoethoxy)phenyl]-1-p-tolyethanol	745	92
174	4-[4-(4-Chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl) butan-1-one	369	185
175	2-(4-Chlorophenyl)-3-methylbutane-2,3-diol	552	95
176	2-(4-Chlorophenyl)-3-methyl-1,3-thiazinan-4-one 1,1-dioxide	162	91
177	2-[2-(4-Chlorophenyl)-2-phenylacetyl]indan-1,3-dione	171	93
178	2-[1-(4-Chlorophenyl)-1-phenylethoxy]ethyl-(dimethyl)amine	181	94
179	Chloropicrine	736	325
180	3-(4-Chloro-3-sulphamoylphenyl)-3-184, hydroxyisoindolin-1-one	186	262
181	Chlorphenoxamine (INN)	178	94
182	Chlorpromazine (INN)	(559)	320
183	Chlorpropamide (INN)	615	79
184	Chlorprothixene (INN) and its salts	167	84
185	Chlorthalidone (INN)	180, 186	262
186	Chlorthalidone	180, 185	262

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
187	Chlorzoxazone (INN)	164	82
188	Cholecalciferol	(760)	335
189	Choline salts and their esters e.g. choline chloride	-	168
190	Chromium, chromic acid and its salts	-	97
191	Chrysoidine citrate hydrochloride	563	81
192	Cinchocaine (INN) and its salts	129	129
193	Cinchophen (INN), its salts and derivatives and salts of these derivatives	578	8
194	<i>Claviceps purpurea Tul.</i> , its alkaloids and galenical preparations	318	98
195	Clofenamide (INN)	163	85
196	Clofenotane (INN)	233, 732	123
197	Cobalt benzenesulphonate	-	101
198	Cocculin	590	282
199	Colchicine, its salts and derivatives	-	102
200	Colchicoside and its derivatives	-	103
201	<i>Colchicum autumnale L.</i> and its galenical preparations	-	104
202	Colouring agent CI 12075 and its lakes, pigments and salts	-	397
203	Colouring agent CI 12140	-	378
203a	Colouring agent CI 12150 (Solvent Red 1) when used as a substance in hair dye products		1231
204	Colouring agent CI 13065	-	387
205	Colouring agent CI 15585	-	401
205a	Colouring agent CI 20170 (Acid Orange 24), when used as a substance in hair dye products		1232
206	Colouring agent CI 26105	-	379
206a	Colouring agent CI 27290 (Acid Red 73), when used as a substance in hair dye products		1233
207	Colouring agent CI 42535	-	388

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
208	Colouring agent CI 42555 Colouring agent CI 42555-1 Colouring agent CI 42555-2	-	380
209	Colouring agent CI 42640	-	386
210	Colouring agent CI 61554	-	389
211	Colouring agents CI 45170 and CI 45170:1	-	398
212	Coniferyl benzoate (except natural content of essences)	89	357
213	Coniine	616	290
214	<i>Conium maculatum</i> L. (fruit, powder galenical preparations)	-	99
215	Convallatoxin	-	105
215a	Costus root oil	637a	1133
216	Coumetarol (INN)	454	225
217	Crimidine (ISO)	165, 169	83
218	<i>Croton tiglium</i> (oil)	-	107
218a	Crude and refined coal tars		420
219	Curare and curarine	-	109
220	Curarizants, synthetic	-	110
221	1-(3-Cyano-3,3-diphenylpropyl)-4-ethoxycarbonyl-4-phenylpiperidinium chloride	297	80
221a	Cyclamen alcohol (CAS No. 4756-19-8), when used as a fragrance ingredient	-	425
222	Cyclarbamate (INN)	230	122
223	Cyclizine (INN) and its salts	302	159
224	Cyclobarbitone and its salts	(70)	220
225	Cyclocoumarol	268	234
226	2- $\alpha$ -Cyclohexylbenzyl( <i>N,N,N',N'</i> -tetraethyl)trimethylenediamine	553	112
227	2-Cyclohexyl-3,5-dimethylphenol and its salts	229	113

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
227a	2,2'-[Cyclohexylidenebis[(2-methyl-4,1-phenylene)azo]]bis[4-cyclohexaphenol] (Solvent Yellow 29; CI 21230) (CAS 6706-82-7; EINECS 229-754-0) when used as a substance in hair dye products		1352
228	1-Cyclohexyl-3-( <i>p</i> -methylbenzenesulphonyl)urea	364	100
229	Cyclomenol (INN) and its salts	227	113
230	Cyclopentane-1,1-dimethanol dicarbanilate	222	122
230a	N-Cyclopentyl- <i>m</i> -Aminophenol, when used as a substance in hair dye products.		1225
231	Cyclophosphamide (INN) and its salts	106, 109	88
232	<i>Datura stramonium</i> L. and its galenical preparations	652	301
233	DDT (ISO) ( <i>pp'</i> -DDT)	196, 732	123
234	Deanol aceglumate (INN)	279	3
235	Decamethonium bromide (INN)	(236)	214
236	Decamethylenebis (trimethylammonium) salts	235	214
237	Dextromethorphan (INN) and its salts	458	226
238	Dextropropoxyphene (INN)	281	116
239	<i>O,O</i> -Diacetyl- <i>N</i> -allyl- <i>N</i> -normorphine	-	117
240	2,4-Diaminoanisole (CI 76050) and its salts	456, 462	376
241	2,5-Diaminoanisole and its salts	457, 461	377
242	1,2-Diaminobenzene and its salts	571	363
242a	3,4 Diaminobenzoic acid, when used as a substance in hair dye products		1229
242b	4,5-Diamino-1-((4-Chlorophenyl)Methyl)-1H-Pyrazole Sulfate, when used as a substance in hair dye products		1218
242c	2,4-Diaminodiphenylamine, when used as a substance in hair dye products		1214
243	<i>p,p'</i> -Diaminodiphenyl	84	26
243a	2,4-Diamino-5-methylphenetol and its HCl salt, when used as a substance in hair dye products		1227
243b	4,5-Diamino-1-Methylpyrazole and its HCl salt, when used as a substance in hair dye products		1217

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
243c	4,4'-Diaminodiphenylamine (CAS No 537-65-5) and its salts, when used as a substance in hair dye products		1309
243d	1,4-Diamino-2-methoxy-9,10-anthracenedione (CAS No 2872-48-2) (Disperse Red 11) and its salts when used as a substance in hair dye products		1301
243e	2,4-Diamino-5-methylphenoxyethanol (CAS No 141614-05-3) and its salts, when used as a substance in hair dye products		1314
244	2,4-Diaminophenylethanol and its salts	-	407
245	1,4:3,6-Dianhydrosorbitol 2,5-dinitrate	422	148
245a	4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one; 4',5'-Dibromofluorescein; (Solvent Red 72) (CAS 596-03-2; EINECS 209-876-0) and its disodium salt (CI 45370 (CAS 4372-02-5; EINECS 224-468-2 when used as a substance in hair dye products		1333
246	5-( $\alpha,\beta$ -Dibromophenethyl)-5-methylhydantoin	-	119
247	Dibromosalicylanilides	248, 444	351
248	Dibromsalan (INN)	(247)	351
248a	2,2'[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutanamide] (CAS 6358-85-6) (Pigment Yellow 12) and its salts, when used as a substance in hair dye products		1263
248b	2,2'[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide] (Pigment Yellow 13; CI 21100) (CAS 5102-83-0; EINECS 225-822-9) when used as a substance in hair dye products		1351
248c	8,18-Dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine (Pigment Violet 23; CI 51319 (CAS 6358-30-1; EINECS 228-767-9) when used as a substance in hair dye products		1360
248d	Dibutyl phthalate CAS No 84-74-2		675
249	Dichloroethanes	330, 335	125
250	Dichloroethylenes	7, 758	126
251	2,3-Dichloro-2-methylbutane	46	36
252	Dichlorosalicylanilides	-	349

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
253	Dicoumarin	254, 470	231
254	Dicoumarol (INN)	253, 470	231
255	Diethanolamine	(111, 641)	411
256	2-(Diethylaminoethoxy)ethyl-phenylpiperidine-1-acetate dimethiodide	599	137
257	2-Diethylaminoethyl 3-amino-4-butoxybenzoate and its salts	102	23
258	2-Diethylaminoethyl benzilate	73	157
259	2-Diethylaminoethyl 4-ethoxybenzoate and its salts	411, 537	179
260	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts	-	128
261	2-Diethylaminoethyl phenyl(piperidino) acetate	104	287
261a	N,N-Diethyl- <i>m</i> -Aminophenol, when used as a substance in hair dye products		1223
261b	4-Diethylamino- <i>o</i> -toluidine (CAS No 148-71-0) and its salts when used as a substance in hair dye products		1310
262	3-Diethylaminopropyl cinnamate	-	130
262a	Diethylene Glycol (DEG), for traces level see Annex III 2,2'-oxydiethanol CAS No 111-46-6 ;EC No 203-872-2		1370
262b	Diethyl maleate (CAS No. 141-05-9) when used as a fragrance ingredient	-	426
263	Diethyl 4-nitrophenyl phosphate	535	170
264	O,O-Diethyl O-4-nitrophenyl phosphorothioate	536	131
264a	N,N-Diethyl- <i>p</i> -phenylenediamine (CAS No 93-05-0) and its salts, when used as a substance in hair dye products		1311
265	Difenclozazine (INN)	567	270
266	Digitaline and all heterosides of <i>Digitalis purpurea</i> L.	-	134
267	4,5 Dihydrobenzimidazol-4-one	87, 88	48
267a	Dihydrocoumarine (CAS No. 119-84-6) when used as a fragrance ingredient	-	427
268	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H 5H-pyrano[3,2-c][1]-benzopyran-5-one	225	234

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
268a	5,12-Dihydroquino[2,3-b]acridine-7,14-dione(Pigment Violet 19; CI 73900) (CAS 1047-16-1; EINECS 213-879-2) when used as a in hair dye products		1366
269	Dihyrotachysterol (INN)	-	342
269a	2,3-Dihydro-2,2-dimethyl-6-[(4-(phenylazo)-1-naphthalenyl)azo]-1H-Pyrimidine (CAS No 4197-25-5)(Solvent Black 3) and its salts, when used as a substance in hair dye products		1265
270	3,4-Dihydro- <i>a</i> -(methylaminomethyl)benzyl alcohol	14, 315	14
270a	1,2-Dihydroxyanthraquinone (Pigment Red 83; CI 58000) (CAS 72-48-0; EINECS 200-782-5) when used as a substance in hair dye products		1361
270b	1,4-Dihydroxybenzene (Hydroquinone)(CAS 123-31-9; EINECS 204-617-8) when used as a substance in hair dye products		1339
270c	2,4-Dihydroxy-3-methylbenzaldehyde (CAS No. 6248-20-0) when used as a fragrance ingredient	-	428
270d	2,6-Dihydroxy-4-methylpyridine (CAS No 4664-16-8) and its salts, when used as a substance in hair dye products		1245
270e	1,4-Dihydroxy-5,8-bis[(2-hydroxyethyl)amino]anthraquinone (CAS No 3179-90-6) (Disperse Blue 7) and its salts when used as a substance in hair dye products		1302
270f	3',6'-Dihydroxy-4',5'-diiodospiro(isobenzofuran-1(3H),9'-[9H] xanthene)-3-; (Solvent Red 73) (CAS 38577-97-8; EINECS 254-010-7) and its sodium salt (Acid Red 95; CI 45425) (CAS 33239-19-9; EINECS 251-419-2 when used as a substance in hair dye products		1336
271	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin	-	207
271a	4-(2,4-Dihydroxyphenylazo)benzenesulphonic acid (CAS 2050-34-2; EINECS 218-087-0 and its sodium salt (Acid Orange 6; CI 14270) (CAS 547-57-9; EINECS 208-924-8) when used as a substance in hair dye products		1330
272	1-(3,4-Dihydroxyphenyl)-2-ethylamino-propan-1-ol and its salts	294	136
273	1-(3,4-Dihydroxyphenyl)-2-41isopropylaminoethanol	418	17

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
273a	2-(3,6-Dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)-benzoic acid; Fluorescein, 2',4',5',7'-tetrabromo-;(Solvent Red 43) (CAS 15086-94-9;EINECS 239-138-3), its disodium salt (Acid Red 87; CI 45380) (CAS 17372-87-1;EINECS 241-409-6) and its aluminium salt (Pigment Red 90:1 Aluminium lake) (CAS 15876-39-8; EINECS 240-005-7) when used as a substance in hair dye products		1334
274	Diisopropanolamine	(111, 641)	411
275	5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihyopiodite	413	361
276	Dimethoxane	286	368
277	4-[2-(3,4-Dimethoxyphenyl)ethyl]-1-(2-chlorophenyl)piperazine and its salts	439	141
278	Dimethylamine	-	142
279	2-Dimethylaminoethyl <i>N</i> -acetylglutamate	234	3
280	2-Dimethylaminoethyl p-butylaminobenzoate and its salts	688	63
281	(+)-4-Dimethylamino-3-methyl-1,2-diphenyl-2-propionyloxybutane	238	116
282	1-Dimethylaminomethyl-1-methylpropyl benzoate and its salts	50	50
282a	5-((4-(Dimethylamino)phenyl)azo)-1,4-dimethyl-1H-1,2,4-triazolium and its salts when used as a substance in hair dye products		1292
283	2-Dimethylaminopropiophenone and its salts	446	145
284	3-(3-Dimethylaminopropylidene)-1,2:4,5 dibenzocyclohepta-1,4-diene and its salts	42	146
285	1,1-Dimethylbiguanide and its salts	448	147
285a	Dimethyl citraconate (CAS No. 617-54-9) when used as a fragrance ingredient	-	431
286	2,6-Dimethyl-1,3-dioxan-4-yl acetate	276	368
286a	7,11-Dimethyl-4,6,10-dodecatrien-3-one (CAS No. 26651-96-7) when used as a fragrance ingredient	-	432
287	Dimethylformamide	-	355
288	1,5-Dimethylhexylamine and its salts	34, 524	28

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
288a	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) (CAS No. 40607-48-5) when used as a fragrance ingredient	-	429
288b	N,N'-Dimethyl-N-Hydroxyethyl-3-nitro-p-phenylenediamine (CAS No 10228-03-2) and its salts, when used as a substance in hair dye products		1288
289	1,3-Dimethylpentylamine and its salts	35, 472	30
289a	N,N-Dimethyl-2,6-Pyridinediamine and its HCl salt, when used as a substance in hair dye products		1224
289b	N,N-Dimethyl-p-phenylenediamine (CAS No 99-98-9) and its salts, when used as a substance in hair dye products		1312
290	Dimethyl sulfoxide (INN)	-	338
290a	4,6-Dimethyl-8- <i>tert</i> -butylcoumarin (CAS No. 17874-34-9) when used as a fragrance ingredient	-	430
290b	6,10-Dimethyl-3,5,9-undecatrien-2-one (CAS No. 141-10-6) when used as a fragrance ingredient	-	433
291	Dimevamide (INN) and its salts	298	153
292	Dinitrophenol isomers	-	151
292a	Diphenylamine (CAS No. 122-39-4) when used as a fragrance ingredient	-	434
293	Dioxane	-	343
294	Dioxethedrin (INN) and its salts	272	136
295	2,5-Dioxo-3,3-diethyl-5-methylpiperidine and its salts	484	133
296	Diphenhydramine (INN) and its salts	83	339
297	Diphenoxylate hydrochloride (INN)	221	80
298	2,2-Diphenyl-4-dimethylaminovaleramide and its salts	291	153
299	5,5-Diphenyl-4-imidazolidone	-	160
300	4-Diphenylmethoxy-1-methylpiperidine and its salts	306	154
301	3-Diphenylmethoxytropone and its salts	77	158
302	1-Diphenylmethyl-4-methylpiperazine and its salts	223	159
303	1,2-Diphenyl-4-(2-phenylsulphinylethyl)-pyrazolidine-3,5-dione	662	155
304	<i>a,a</i> -Diphenyl-2-piperidinemethanol and its salts	598	285

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
305	<i>a,a</i> -Diphenyl-4-piperidinemethanol and its salts	67	286
306	Diphenylpyraline (INN) and its salts	300	154
307	2,5-Dipropoxy-3,6-bis(ethyleneimino)-1,4-benzoquinone	410	152
308	4-Dipropylsulphamoylbenzoic acid	607	161
308a	Disperse Red 15, except as impurity in Disperse Violet 1		1241
308b	Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate (Pigment Red 48; CI 15865) (CAS 3564-21-4; EINECS 222-642-2) when used as a substance in hair dye products		1348
308c	Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate (Ponceau SX; CI 14700) (CAS 4548-53-2; EINECS 224-909-9 when used as a substance in hair dye products		1341
308d	Disodium [29H,31H-phthalocyaninedisulphonato (4-)-N29,N30,N31, N32]cuprate(2-) (Direct Blue 86; CI 74180) (CAS 1330-38-7; EINECS 215-537-8) when used as a substance in hair dye products		1368
309	Disulfiram (INN)	700, 711	162
310	Dithio-2,2'-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) - (pyrithione disulphide + magnesium sulphate)	626	396
311	Doxylamine (INN) and its salts	577	176
312	Emetine, its salts and derivatives	-	163
313	Endrin (ISO)	373	196
314	Ephedrine and its salts	-	164
315	Epinephrine (INN)	14, 270	14
316	1,2-Epoxybutane	-	400
317	Ergocalciferol (INN)	140, (760)	335
318	Ergot and its alkaloids	194	98
319	Eserine and its salts	587	166
319a	Ethanaminium, N-(4-[bis[4-(diethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene)-N-ethyl- and its salts, when used as a substance in hair dye products		1271

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
319b	Ethanaminium, N-[4-[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene-2,5-cyclohexadien-1-ylidene]-N-ethyl- and its salts, when used as a substance in hair dye products		1328
319c	Ethanaminium, N-[4-[(4-(diethylamino)phenyl)phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl- and its salts, when used as a substance in hair dye products		1299
319d	Ethanol,2,2'-iminobis-,reaction products with epichlorohydrin and epichlorohydrin and 2-nitro-1,4-benzenediamine (CAS No 68478-64-8) (CAS 158571-58-5) (HC Blue No 5) and its salts, when used as a substance in hair dye products		1255
319e	2,2'-(1,2-Ethenediyl)bis[5-((4-ethoxyphenyl)azo)benzenesulfonic acid] and its salts, when used as a substance in hair dye products		1264
319f	Ethanaminium, N-(4-((4-(diethylamino)phenyl)(2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl-,hydroxide, inner salt, sodium salt (Acid Blue 1; CI 42045) (CAS 129-17-9; EINECS 204-934-1) when used as a substance in hair dye products.		1355
319g	Ethanaminium, N-(4-((diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide,inner salt,calcium salt (2:1) (Acid Blue 3; CI 42051) (CAS 3536-49-0;EINECS222-573-8) when used as a substance in hair dye products		1356
320	Ethionamide (INN)	336	319
321	Ethoheptazine (INN) and its salts	477	173
322	Ethopropazine (INN) and its salts	(559)	320
322a	7-Ethoxy-4-methylcoumarin		1134
323	4-Ethoxyphenol	97, 459	178
323a	4-[(4-Ethoxyphenyl)azo]naphthol(Solvent Red 3; CI 12010) (CAS 6535-42-8;EINECS 229-439-8) and its salts when used as a substance in hair dye products		1344
324	4-Ethoxy- <i>m</i> -phenylenediamine and its salts	-	406
324a	Ethyl acrylate (CAS No. 140-88-5) when used as a fragrance ingredient	-	435
324b	4-Ethylamino-3-nitrobenzoic acid (CAS No 2788-74-1) (N-Ethyl-3-Nitro PABA) and its salts, when used as a substance in hair dye products		1290

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
325	2-Ethylamino-5-phenyloxazolin-4-one	345	180
326	Ethyl bis (4-hydroxycoumarinyl)acetate and salts of the acid	327	204
327	Ethyl bis (4-hydroxy-2-oxo-1-benzopyran-3-yl)acetate and salts of the acid	326	204
328	Ethyl chloride	168	96
329	Ethyl 1,3-dimethyl-4-phenylazepane-4-carboxylate and its salts	447	171
330	Ethylene chlorides	(249)	125
331	Ethylene oxide	-	182
332	2-Ethyl-2,3-epoxyhexamide and its derivatives	529	165
333	Ethyl <i>p</i> -fluorophenyl sulphone	348	189
333a	3-[[4-[Ethyl(2-Hydroxyethyl)Amino]-2-Nitrophenyl]Amino]-1,2-Propanediol (CAS No 114087-41-1) and its salts, when used as a substance in hair dye products		1327
334	Ethyl 1-(2-hydroxy-2-phenylethyl)-4-phenylpiperidine-4-carboxylate and its salts	531	172
335	Ethylidene dichloride	(249)	125
336	3-Ethylisothionicotinamide	320	319
337	3-Ethyl-3-methylglutarimide and its salts	72, 338	183
338	4-Ethyl-4-methylpiperidine-2,6-dione and its salts	72, 337	183
339	2-Ethyl-3-methylvaleramide	754	184
340	Ethylphenacetamide	554, 566	272
341	2-Ethyl-2-phenylglutarimide and its salts	362	181
342	3'-Ethyl-5',6',7,8'-tetrahydro-5',6',8',8'-tetramethyl-2'-acetonephthone	9	362
343	Ethyl urocanate	(406)	418
344	Fenadiazole (INN)	527	208
345	Fenozolone (INN)	325	180
346	Fenylramidol (INN)	576, 580	274
346a	Fig Leaf absolute ( <i>Ficus Carica</i> ) (CAS No. 68916-52-9) when used as a fragrance ingredient	-	436

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
347	Fluanisone (INN)	351	187
348	Fluoresone (INN)	333	189
349	4'-Fluoro-4-[4-hydroxy-4-(a,a,a-trifluoro- <i>m</i> -tolyl)piperino]butyrophenone	739	188
350	6-Fluoro-16-methyl-11 $\beta$ ,17 $\alpha$ ,21-trihydroxypregna-1,4-diene-3,20-dione	534	186
351	1-(4-Fluorophenyl)-4-[4-(2-methoxyphenyl)-1-piperazinyl]butan-1-one	347	187
352	5-Fluoropyrimidine-2,4-dione	353	190
353	Fluorouracil (INN)	352	190
354	Fluphenazine (INN)	(559)	320
355	Furazolidone (INN)	512	252
356	Furfuryltrimethylammonium salts	358	192
357	Furocoumarines (e.g. trioxysalan, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1mg/kg	99, 463, 621, 744	358
358	Furtrethonium iodide (INN)	(356)	192
359	Galantamine (INN)	-	193
360	Gallamine triethiodide (INN)	517	329
361	Glucocorticoids	101	300
362	Glutethimide (INN) and its salts	341	181
363	Glycerol trinitrate	513, 613	253
364	Glycyclamide (INN)	228	100
365	Gold salts	-	296
366	Guaifenesin (INN)	460	230
367	Guanethidine (INN) and its salts	368	259
368	<i>N</i> -(2-Guanidinoethyl)azocane and its salts	367	259
369	Haloperidol (INN)	174	185
369a	HC Green No 1		1238

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
369b	HC Orange No 3		1237
369c	HC Red No 8 and its salts		1239
369d	HC Yellow No 11		1236
370	HCH (ISO) ( <i>gamma</i> -HCH)	103, 372, 429	195
371	HETP	378	316
372	1,2,3,4,5,6-Hexachlorocyclohexane	103, 370, 429	195
373	(1 <i>R</i> ,4 <i>S</i> ,5 <i>R</i> ,8 <i>S</i> )-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethanonaphthalene	313	196
374	Hexachloroethane	-	197
375	3,3',4,4',6,6'-Hexachloro-2,2'-methylenediphenol	376	371
376	Hexachlorophene (INN)	375	371
377	(1 <i>R</i> ,4 <i>S</i> ,5 <i>R</i> ,8 <i>S</i> )-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethanonaphthalene	416	198
378	Hexaethyl tetraphosphate	371	316
378a	Hexahydrocoumarin		1135
379	(1 <i>R</i> ,2 <i>S</i> )-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride	142	70
380	(3 <i>S</i> ,5a <i>R</i> ,9b <i>S</i> )-3,3a,4,5,5a,9b-Hexahydro-3,5a,9-trimethylnaphthol[1,2- <i>b</i> ]furan-2,8-dione	637	217
381	Hexamethonium bromide (INN)	(382)	124
382	Hexamethylenebis(trimethylammonium) salts	381	124
383	Hexapropymate (INN)	617	115
383a	3H-Indolium, 2-(2-((2,4-dimethoxyphenyl)amino)ethyl)-1,3,3-trimethyl- and its salts when used as a substance in hair dye products		1273
383b	3H-Indolium, 2-[[[(4-methoxyphenyl)methylhydrazono]methyl]-1,3,3-trimethyl- and its salts, when used as a substance in hair dye products		1272
383c	(29H,31H-Phthalocyaninato (2-)-N29,N30,N31,N32)copper (Pigment Blue 15;CI 74160) (CAS 147-14-8;EINECS 205-685-1 when used as a substance in hair dye products		1367

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
384	Hydrastine, hydrastinine and their salts	-	199
385	Hydrazides and their salts	-	200
386	Hydrazine, its derivatives and their salts	-	201
387	2-Hydrazino-octane and its salts	522	202
387a	Hydroabietyl alcohol (CAS No. 13393-93-6) when used as a fragrance ingredient	-	440
388	Hydrocyanic acid and its salts	390, 409, 602, 643	111
389	Hydrofluoric acid and its normal salts, its complexes and hydrofluorides (except those given in Annex III, Part 1)	-	191
390	Hydrogen cyanide and its salts	388, 409, 602, 643	111
391	Hydroquinone and its monobenzyl, monoethyl, and monomethyl ethers	-	-
391a	5-Hydroxy-1,4-benzodioxane (CAS No 10288-36-5) and its salts, when used as a substance in hair dye products		1246
391b	Hydroxyethylaminomethyl-p-aminophenol (CAS No 110952-46-0) and its salts when used as a substance in hair dye products		1316
391c	Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No 122252-11-3) and its salts, when used as a substance in hair dye products		1320
391d	3-[[4-[(2-Hydroxyethyl)Methylamino]-2-Nitrophenyl]Amino]-1,2 Propanediol (CAS No 173994-75-7) and its salts, when used as a substance in hair dye products		1326
391e	1-Hydroxy-2,4-diaminobenzene (2,4-Diaminophenol) (CAS 95-86-3; EINECS 202-459-4) and its dihydrochloride salt (2,4- Diaminophenol HCl) (CAS 137-09-7; EINECS 205-279-4) when used as a substance in hair dye products		1338
392	7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl]theophylline	763	135
392a	4-Hydroxyindole, when used as a substance in hair dye products		1220
392b	3-Hydroxy-4-[(2-hydroxynaphthyl)azo]-7-nitronaphthalene-1-sulfonic acid (CAS No 16279-54-2) and its salts, when used as a substance in hair dye products		1323
393	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts	740	5

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
394	3-[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]propionic acid and its salts	714	9
395	2-Hydroxy-3-(2-methoxyphenyl) propylcarbamate	451	205
396	1-Hydroxymethyl-1-cyclohexylacetic acid, sodium salt	644	114
397	4-Hydroxy-3-[4-nitrophenyl]-3-oxobutyl coumarin	1	254
398	8-Hydroxy-5-nitroquinoline and its salts	516	209
398a	3-Hydroxy-N-(o-toyl)-4-[2,4,5-trichlorophenyl]azo]naphthalene-2-carboxamide (Pigment Red 112; CI 12370) (CAS 6535-46-2; EINECS 229-440-3) and its salts when used as a substance in hair dye products		1346
399	4-Hydroxy-3-(3-oxo-1-phenylbutyl) coumarin and its salts	3, 761	203
399a	2-(6-Hydroxy-3-oxo-(3H)-xanthen-9-yl)benzoic acid; Fluorescein CAS 2321-07-5; EINECS 219-031-8 and its disodium salt (Acid yellow 73 sodium salt; CI 45350) (CAS 518-47-8; EINECS 208-253-0 when used as a substance in hair dye products		1332
399b	3-Hydroxy-4-(phenylazo)-2-naphthoic acid (CAS 27757-79-5; EINECS 248-638-0 and its calcium salt (Pigment Red 64:1; CI 15800) (CAS 6371-76-2; EINECS 228-899-7), when used as a substance in hair dye products		1331
400	11a-Hydroxypregn-4-ene-3,20-dione and its esters	-	385
400a	Hydroxypyridinone (CAS No 822-89-9) and its salts, when used as a substance in hair dye products		1249
400b	1-Hydroxy-4-(p-toluidino)anthraquinone (Solvent Violet 13; CI 60725) (CAS 81-48-1; EINECS 201-353-5), when used as a substance in hair dye products		1363
401	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in no. 51 of Annex III	115, 532, 631	395
402	Hydroxyzine (INN)	172	240
403	Hyoscine, its salts and derivatives	639	295
404	Hyoscyamine, its salts and derivatives	-	210
405	<i>Hyoscyamus niger</i> L. (leaves, seeds, powder and galenical preparations)	-	211
406	3-Imidazol-4-ylacrylic acid and its ethyl ester	343, 752	418

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
407	2-Imino-5-phenyloxazolidin-4-one and its salts	539	212
407a	( $\mu$ -((7,7'-Iminobis(4-hydroxy-3-((2-hydroxy-5-(N-methylsuphamoyl)phenyl)azo)naphthalene-2-sulphonato))(6-)))dicuprate(2-) and its salts, when used as a substance in hair dye products		1268
408	Imperatorin	466	34
409	Inorganic cyanides	(388, 390), 602, 643	111
410	Inproquone (INN)	307	152
411	Intracaine and its salts	259, 537	179
412	Iodine	-	213
413	Iodothymol	275	361
414	Ipecacuanha ( <i>Cephaelis ipecacuanha</i> Brot. and related species) (roots, powder and galenical preparations)	-	215
414a	1,3-Isobenzofurandione, reaction products with methylquinoline and quinoline (Solvent Yellow 33;CI 47000) (CAS 8003-22-3;EINECS 232-318-2) when used as a substance in hair dye products.		1358
415	Isocarboxazide (INN)	94	52
416	Isodrin (ISO)	377	198
417	Isometheptene (INN) and its salts	464	228
418	Isoprenaline (INN)	273, 421	17
419	Isopropamide iodide (INN)	(146)	156
419a	6-Isopropyl-2-decahydronaphthalenol (CAS No. 34131-99-2) when used as a fragrance ingredient	-	441
420	(2-Isopropylpent-4-enoyl)urea	60	216
421	Isoproterenol	273, 418	17
422	Isosorbide dinitrate (INN)	245	148
423	<i>Juniperus sabina</i> L. (leaves, essential oil and galenical preparations)	-	294
423a	Laccaic Acid (CI Natural Red 25) (CAS No 60687-93-6) and its salts, when used as a substance in hair dye products		1279
424	Laurel oil	425	359
425	<i>Laurus nobilis</i> L. (oil from seeds)	424	359

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
426	Lead and its compounds		289
427	Levophacetoperane and its salts	595	284
428	Lidocaine (INN) (Lignocaine)	-	399
429	Lindane	103, 370, 372	195
430	<i>Lobelia inflata</i> L. and its galenical preparations	-	218
431	Lobeline (INN) and its salts	113	219
432	LSD	(434, 435)	127
433	Lupinidine and its salts	649	299
434	Lysergic acid diethylamide and its salts	432, 435	127
435	Lysergide (INN) and its salts	432, 434	127
436	Malononitrile	-	149
437	Mannomustine (INN) and its salts	105	89
438	Mecamylamine (INN)	699	229
439	Mefeclozazine (INN) and its salts	277	141
440	Mephenesin (INN) and its esters	719	322
441	Meproamate (INN)	482	236
442	Mercury and its compounds, except those listed in Annex VI	-	221
443	Mescaline and its salts	741	222
444	Metabromsalan (INN)	(247)	351
445	Metaldehyde	601	223
446	Metamfepramone (INN) and its salts	283	145
447	Metethoheptazine (INN) and its salts	329	171
448	Metformin (INN) and its salts	285	147
449	Methapyrilene (INN) and its salts	625	144
450	Metheptazine (INN) and its salts	469	174
451	Methocarbamol (INN)	395	205
452	Methohexitone and its salts	(70)	220

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
453	Methotrexate (INN)	33	6
454	2-[4-Methoxybenzyl- <i>N</i> -(2-pyridyl)amino]-ethyl dimethylamine maleate	623	346
455	1-Methoxy-2,2-bis(4-hydroxy-3-coumarinyl)ethane	216	225
455a	7-Methoxycoumarin (CAS No. 531-59-9) when used as a fragrance ingredient	-	442
456	1-Methoxy-2,4-diaminobenzene and its salts	240, 462	376
457	1-Methoxy-2,5-diaminobenzene and its salts	241, 461	377
457a	<i>N</i> -(2-Methoxyethyl)- <i>p</i> -phenylenediamine and its HCl salt, when used as a substance in hair dye products		1226
457b	2-Methoxymethyl- <i>p</i> -Aminophenol and its HCl salt, when used as a substance in hair dye products		1216
458	(+)-3-Methoxy- <i>N</i> -methylmorphinan and its salts	237	226
458a	2-methoxy-4-nitrophenol (CAS No 3251-56-7) (4-Nitroguaiacol) and its salts, when used as a substance in hair dye products		1251
459	4-Methoxyphenol	97, 323	178
460	3-(2-Methoxyphenoxy)propane-1,2-diol	366	230
460a	4-(4-Methoxy phenyl-3-butene-2-one (CAS No. 943-88-4) when used as a fragrance ingredient	-	443
461	2-Methoxy- <i>p</i> -phenylenediamine and its salts	241, 457	377
462	4-Methoxy- <i>m</i> -phenylenediamine and its salts	240, 456	376
462a	1-(4-Methoxyphenyl)-1-penten-3-one (CAS No. 104-27-8) when used as a fragrance ingredient	-	444
463	Methoxypsoralen (except natural content of essences) In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg		
463a	4-Methoxytoluene-2,5-Diamine and its HCl salt, when used as a substance in hair dye products		1221
463b	6-Methoxy-2,3-Pyridinediamine and its HCl salt, when used as a substance in hair dye products		1212
464	6-Methylamino-2-methylhept-2-ene and its salts	417	228
465	2-Methyl-1,2-bis(3-pyridyl)propan-1-one	485	292
466	9-(3-Methoxybut-2-enyloxy)furo-[3,2- <i>g</i> ]chromen-7-one	408	34

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
467	2-Methyl-6-chloroanilide of n-butylaminoacetic acid and its salts	126	90
467a	7-Methylcoumarin (CAS No. 2445-83-2) when used as a fragrance ingredient	-	446
468	1-Methyl-2,4-diaminobenzene and its salts	478	364
469	Methyl 1,2-dimethyl-4-phenylazepane-4-carboxylate and its salts	450	174
470	3,3-Methylenebis-(4-hydroxycoumarin)	253, 254	231
470a	Methyleugenol (CAS No. 93-15-2) except for normal content in the natural essences used and provided that the concentration does not exceed: * 0.01% in fine fragrance * 0.004% in eau de toilette * 0.002% in fragrance cream * 0.001% in rinse-off products * 0.0002% in other leave-on products and oral hygiene products	-	451
470b	3,4-Methylenedioxyaniline (CAS 14268-66-7) and its salts, when used as a substance in hair dye products		1248
470c	3,4-Methylenedioxyphenol (CAS No 533-31-3) and its salts, when used as a substance in hair dye products		1247
471	2-Methylheptylamine and its salts	-	227
471a	5-Methyl-2,3-hexanedione (CAS No. 13706-86-0) when used as a fragrance ingredient	-	447
472	4-Methyl-2-hexylamine and its salts	35, 289	30
473	1-Methylimidazole-2-thiol	475, 705	233
474	N,N'-[(Methylimino)diethylene]bis(ethyldimethylammonium)] salts	68	121
475	1-Methyl-2-mercaptoimidazole	473, 705	233
476	Methylphenidate (INN) and its salts	573	175
477	1-Methyl-4-phenyl-4-carbethoxyhexamethyleneimine and its salts	321	173
477a	4,4'-[(4-Methyl-1,3-phenylene)bis(azo)]bis[6-methyl-1,3-benzenediamine](CAS No 4482-25-1) (Basic Brown 4) and its salts, when used as a substance in hair dye products		1296
478	4-Methyl-m-phenylenediamine and its salts	468	364
479	2-Methyl-m-phenylenediamine	-	413
480	3-Methyl-2-phenylmorpholine, its derivatives and salts	556	232

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
481	2-Methyl-2-propyl-1-isopropylcarbamoyloxy-3-carbamoyloxypropane	152	235
482	2-Methyl-2-propyltrimethylene dicarbamate	441	236
483	<i>N</i> -Methyl-1,2,5,6-tetrahydro-3-nicotinic acid methyl ester	61	238
483a	Methyl <i>trans</i> -2-butenate (CAS No. 623-43-8) when used as a fragrance ingredient	-	445
483b	1-Methyl-2,4,5-trihydroxybenzene (CAS No 1124-09-0) and its salts, when used as a substance in hair dye products		1244
484	Methypylon (INN) and its salts	295	133
485	Metyrapone (INN)	465	292
486	Minoxidil (INN), its salts and derivatives	597	372
486a	m-Phenylenediamine,4-(phenylazo)-, (CAS No 495-54-5) and its salts when used as a substance in hair dye products		1293
487	Mofebutazone (INN)	134	64
488	Monobenzene (INN)	97, (323)	178
489	Morpholine and its salts	-	344
489a	Moskene	544a	421
490	Musk ambrette	133	414
490a	Musk tibetene	137a	422
491	Mustine and its salts	107, 161	87
492	Mustine <i>N</i> -oxide and its salts	108	86
492a	Exudation of <i>Myroxylon pereirae</i> (Royle) Klotzch (Peru balsam, crude); CAS No 8007-00-9 when used as a fragrance ingredient	548a	1136
493	Nalorphine (INN), its salts and ethers	21	20
494	Naphazoline (INN) and its salts	500	244
494a	1,7-Naphthalenediol, when used as a substance in hair dye products		1228
494b	2,3- Naphthalenediol, when used as a substance in hair dye products		1213
494c	2,7-Naphthalenedisulfonic acid, 5-(acetylamino)-4-hydroxy-3- ((2-methylphenyl)azo)- and its salts, when used as a substance in hair dye products		1295

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
494d	2-Naphthalenesulfonic Acid, 7-(benzoylamino)-4-hydroxy-3-[[4-[(4-sulfophenyl)azo]phenyl]azo]-and its salts, when used as a substance in hair dye products		1267
494e	2-Naphtalenesulfonic acid, 7,7'-(carbonyldiimino)bis(4-hydroxy-3-[[2-sulfo-4-[(4-sulfophenyl)azo]phenyl]azo]-, (CAS 25188-41-4) and its salts, when used as a substance in hair dye products		1270
495	2-Naphthol	496	241
496	$\beta$ -Naphthol	495	241
497	1- and 2-Naphthylamines and their salts	498	242
498	$\alpha$ and $\beta$ -Naphthylamines and their salts	497	242
499	3-(1-Naphthyl)-4-hydroxycoumarin	-	243
500	2-(1-Naphthylmethyl)-2-imidazoline and its salts	494	244
501	Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961	-	306
502	Narcotine and its salts	520	258
503	Neodymium and its salts	-	309
504	Neostigmine and its salts	504a	245
504a	N1-(2-Hydroxyethyl)-4-nitro-o-phenylenediamine (CAS No 56932-44-6) (HC Yellow No 5) and its salts when used as a substance in hair dye products		1285
505	Nicotine and its salts	-	246
505a	Nigrosine spirit soluble (CAS No 11099-03-9) (Solvent Black 5), when used as a substance in hair dye products		1274
505b	Nigrosine (CI 50420) (CAS 8005-03-6) when used as a substance in hair dye products		1359
506	Nitrites, inorganic (except sodium nitrite)	-	248
506a	3-Nitro-4-aminophenoxyethanol (CAS No 50982-74-6) and its salts, when used as a substance in hair dye products		1250
507	Nitrobenzene	-	249
508	Nitrocresols and their alkali metal salts	-	250

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
509	Nitroderivatives of carbazole	147	72
510	Nitrofurantoin (INN)	511	251
511	<i>N</i> -(5-Nitro-2-furfurylidene)-1-aminohydantoin	510	251
512	3-(5-Nitrofurfurylideneamino)oxazolidin-2-one	355	252
513	Nitroglycerine	363, 612	253
513a	6-Nitro- <i>o</i> -Toluidine		1235
513b	4-Nitro- <i>m</i> -phenylenediamine (CAS No 5131-58-8) and its salts, when used as a substance in hair dye products		1282
513c	2-Nitro- <i>N</i> -hydroxyethyl- <i>p</i> -anisidine (CAS No 57524-53-5) and its salts, when used as a substance in hair dye products		1287
513d	4-[(4-Nitrophenyl)azo]aniline (CAS No 730-40-5) (Disperse Orange 3) and its salts, when used as a substance in hair dye products.		1281
513e	2-Nitro- <i>p</i> -phenylenediamine (CAS No 5307-14-2) and its salts, when used as a substance in hair dye products		1319
513f	6-Nitro-2,5-pyridinediamine (CAS No 69825-83-8) and its salts, when used as a substance in hair dye products		1321
514	Nitrosamines	-	410
515	Nitrostilbenes and their homologues and derivatives	-	256
515a	3-[(2-nitro-4-(trifluoromethyl)phenyl)amino]propane-1,2-diol (CAS No 104333-00-8) (HC Yellow No 6) and its salts, when used as a substance in hair dye products		1324
516	Nitroxoline (INN) and its salts	398	209
516a	<i>N,N'</i> -dihexadecyl- <i>N,N'</i> -bis(2-hydroxyethyl)propanediamide Bishydroxyethyl Biscetyl Malonamide		1243
516b	<i>N</i> -Methyl-1,4-diaminoanthraquinone, reaction products with epichlorohydrin and mono ethanolamine (CAS No 158571-57-4) (HC Blue No 4) and its salts, when used as a substance in hair dye products		1256
516c	<i>N</i> -Methyl-3-nitro- <i>p</i> -phenylenediamine (CAS No 2973-21-9 and its salts, when used as a substance in hair dye products		1284

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
516d	3-(N-Methyl-N-(4-methylamino-3-nitrophenyl)amino)propane-1,2-diol (CAS No 93633-79-5) and its salts, when used as a substance in hair dye products		1289
517	N,N,N,N',N',N'',N'',N''-Nonaethyl-2,2',2''-(benzene-1,2,3-triyltrioxy-tris(ethanaminium) triiodide	360	329
518	Noradrenaline and its salts	32, 519	257
519	Norepinephrine (INN) and its salts	32, 518	257
520	Noscapine (INN) and its salts	502	258
521	Nox vomica and its preparations	(659)	305
521a	N1-(Tris(hydroxymethyl))methyl-4-nitro-1,2-phenylenediamine (CAS No 56932-45-7) (HC Yellow No 3) and its salts, when used as a substance in hair dye products		1286
522	Octamoxin (INN) and its salts	387	202
523	Octamylamine (INN) and its salts	-	267
524	Octadrine (INN) and its salts	34, 288	28
525	Oestrogens	-	260
526	Oleandrin	-	261
527	2-(1,3,4-Oxadiazol-2-yl)phenol	344	208
528	[Oxalylbis(iminoethylene)] bis[(o-chlorobenzyl) diethylammonium] salts	24	132
529	Oxanamide (INN) and its derivatives	332	165
530	2-Oxo-3-isobutyl-9,10-dimethoxy-1,2,3,4,6,7-hexahydro-11bH-benzo[a]quinolizine and its salts	686	139
531	Oxpheneridine (INN) and its salts	334	172
532	Oxyquinoline and its sulphate, except for the uses provided for in entry number 51 in Part 1 of Annex III	115, 401, 631	395
533	Padimate A (INN)	47	381
534	Paramethasone (INN)	350	186
535	Paraoxon	263	170
536	Parathion (ISO)	264	131

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
537	Parethoxycaine (INN) and its salts	259, 411	179
537a	PEG-3,2',2'-di-p-Phenylenediamine		1234
538	Pelletierine and its salts	596	263
539	Pemoline (INN) and its salts	407	212
540	Pentachloroethane	-	264
541	Pentaerythritol chloral	550	266
542	Pentaerithrityl tetranitrate	543, 549	265
543	Pentaeruthrityl tetranitrate (INN)	542, 549	265
544	Pentamethonium bromide (INN)	(545)	120
544a	1,1,3,3,5-Pentamethyl-4,6-dinitroindane	489a	421
545	N,N'-Pentamethylenebis (trimethylammonium) salts	544	120
546	Pentobarbitone and its salts	(70)	220
546a	2-Pentylidenecyclohexanone (CAS No. 25677-40-1) when used as a fragrance ingredient	-	448
547	Perchloroethylene	690	314
548	Perphenazine (INN) and its salts	(559)	320
548a	Peru Balsam, crude ; CAS 8007-00-9 when used as a fragrance ingredient	492a	1136
549	PETN	542, 543	265
550	Petrichloral (INN)	541	266
551	Phenacemide (INN)	562	269
552	Phenaglycodol (INN)	175	95
552a	Phenazinium, 3,7-diamino-2,8-dimethyl-5-phenyl- and its salts, when used as a substance in hair dye products		1322
553	Phenetamine	226	112
554	Pheneturide (INN)	340, 566	272
555	Phenindone (INN)	572	271
556	Phenmetrazine (INN), its derivatives and salts	480	232

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
557	Phenobarbitone and its salts	(70)	220
557a	Phenol		1175
558	Phenolphthalein (INN)	114	417
559	Phenothiazine (INN) and its compounds	182, 322, 354, 548, 609, 611, 708, 738	320
559a	Phenothiazine-5-ium, 3,7-bis(dimethylamino)- and its salts when used as a substance in hair dye products		1306
559b	Phenoxazin-5-ium, 3,7-bis (diethylamino)-, (CAS No 47367-75-9 and its salts when used as substance in hair dye products		1275
560	Phenprobamate (INN)	574	71
561	Phenprocoumon (INN)	575	273
562	<i>N</i> -Phenylacetylurea	551	269
562a	1-((4-Phenylazo)phenylazo)-2-naphthol (Solvent Red 23; CI 26100) (CAS 85-86-9; EINECS 201-638-4) when used as a substance in hair dye products		1353
563	4-Phenylazophenylene-1,3-diamine citrate hydrochloride	191	81
563a	4-(Phenylazo)resorcinol (Solvent Orange 1; CI 11920) (CAS 2051-85-6; EINECS 218-131-9) and its salts, when used as a substance in hair dye products		1343
564	Phenylbutazone (INN)	132	67
565	4-Phenylbut-3-en-2-one	95	356
566	(2-Phenylbutyryl)urea	340, 554	272
567	<i>N</i> -[2-( <i>a</i> -Phenyl- <i>p</i> -chlorobenzyl)-ethyl]morpholine	265	270
568	1-Phenylcyclopentanecarboxylic acid diethylaminoethyl ester and its salts	145	169
569	2-Phenylcyclopropylamine ( <i>trans</i> -form) and its salts	720	324
570	1-Phenyl-2,3-dimethyl-4-isopropylpyrazol-5-one	618	138
571	<i>o</i> -Phenylenediamine and its salts	242	363
572	2-Phenylindane-1,3-dione	555	271
573	<i>a</i> -Phenyl-2-piperidineacetic acid methyl ester and its salts	476	175

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
574	3-Phenylpropyl carbamate	560	71
575	3-( <i>a</i> -Phenylpropyl)-4-hydroxycoumarin	561	273
576	1-Phenyl-2-(2-pyridylamino)ethanol	346, 580	274
577	2-[1-Phenyl-1-(2-pyridyl)ethoxy]-ethyl dimethylamine and its salts	311	176
578	2-Phenylquinoline-4-carboxylic acid, its salts and derivatives and salts of those derivatives	193	8
579	6-Phenyl-2,4,7-triaminopteridine and its salts	723	275
580	Phenylramidol	346, 576	274
581	Phosphides, metal	-	279
582	Phosphorus	-	279
583	4-Phosphoryloxy- <i>N,N</i> -diethyltryptamine	620	278
584	3-Phthalimidopiperidine-2,6-dione and its salts	702	280
585	Phthalylsulphathiazole (INN) and its salts	(676)	307
586	<i>Physostigma venenosum</i> Balf.	139	281
587	Physostigmine and its salts	319	166
588	<i>Phytolacca</i> Spp and their preparations	-	374
588a	Phytonadione [INCI], phytonadione [INN] CAS No 84-80-0/81818-54-4 EC No 201-564-2'		1371
589	Picric acid	743	268
590	Picrotoxin	198	282
591	Pilocarpine and its salts	-	283
592	<i>Pilocarpus jaborandi</i> Holmes and its galenical preparations	-	311
593	Pipazetate (INN) and its salts	594	118
594	2-(2-Piperidinoethoxy)ethyl 10-thia-1,9-diazaanthracene-9-carboxylate and its salts	593	118
595	$\alpha$ -Piperidin-2-ylbenzyl acetate, laevorotatorythreo-form and its salts	427	284
596	1-(2-Piperidyl)propan-2-one and its salts	538	263

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
597	6-(Piperidiny)-2,4-pyrimidinediamine-3-oxide, its salts and derivatives	486	372
598	Pipradrol (INN) and its salts	304	285
599	Piprocuarium (INN)	256	137
600	Poldine metisulfate (INN) (Poldine methylsulphate)	86	239
601	Polyacetaldehyde	445	223
601a	Polychloro copper phthalocyanine (Pigment Green 7; CI 74260) (CAS 1328-53-6; EINECS 215-524-7) when used as a substance in hair dye products		1369
602	Potassium cyanide	(388, 390, 409)	111
603	Potassium nitroferrocyanide	(15), 604	255
604	Potassium nitroprusside	(15), 603	255
605	Pramocaine (INN)	606	405
606	Pramoxine	605	405
607	Probenecid (INN)	308	161
608	Procainamide (INN) and its salts and derivatives	29	25
609	Prochlorperazine (INN) and its salts	(559)	320
610	Progestogens	-	194
611	Promazine (INN) and its salts	(559)	320
612	Promethazine (INN) and its salts	(559)	320
613	Propane-1,2,3-triyl trinitrate	363, 513	253
614	Propatylnitrate (INN)	112	206
615	1-Propyl-3-(4-chlorobenzenesulphonyl) urea	183	79
616	2-Propylpiperidine	213	290
617	1-(2-Propynyl)cyclohexyl carbamate	383	115
618	Propyphenazone (INN)	570	138
619	<i>Prunus laurocerasus</i> L.	158	291
620	Psilocybine (INN)	583	278
621	Psoralen (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg	(357)	358
622	<i>Pyrethrum album</i> L. and its galenical preparations	-	345
623	Pyrianisamine maleate	454	346

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
624	Pyribenzamine	98, 746	347
625	2-(N-2-Pyridyl-N-2-thienylamino)ethyl-dimethylamine and its salts	449	144
626	Pyrithione disulphide + magnesium sulphate	310	396
627	Pyrithione sodium (INNM)	-	369
628	Pyrocatechol	80, 154	408
629	Pyrogallol	81	409
630	Quinalbarbitone and its salts	(70)	220
631	Quinolin-8-ol except for the uses provided for in entry number 51 in Part 1 of Annex 11	(401, 532)	395
632	Radioactive substances The presence of natural radioactive substances and of radioactive substances caused by artificial contamination from the environment is permitted, provided that the radioactive substances are not enriched for the manufacture of cosmetic products and that their concentration falls within the limits set in the Directive laying down the basic standards for the protection of the health of workers and the general public against dangers arising from ionising radiations (OJ No. 11, 20.2.1959, p. 221/59)	-	293
633	<i>Rauwolfia serpentina</i> alkaloids and their salts	634	15
634	Reserpine (INN) and its salts	(633)	15
635	Retinoic acid and its salts	722, 759	375
636	Safrole, except for normal content in the natural essences used and provided the concentration does not exceed: a) 100 ppm in the finished product b) 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children	-	360
637	$\alpha$ -Santonin	380	214
637a	<i>Saussurea lappa</i> Clarke	215a	1133
638	<i>Schoenocaulon officinale</i> Lind. (seeds and galenical preparations)	-	332
639	Scopolamine, its salts and derivatives	403	295
640	Secbutobarbitone and its salts	(70)	220
641	Secondary dialkanolamines	111, 255, 274	411

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
642	Selenium and its compounds, with the exception of selenium disulphide under the conditions set out in Part 1 of Annex III, entry number 49	-	297
642a	i) Skull, including the brain and eyes, tonsils and spinal cord of bovine animals aged over 12 months, the intestines from the duodenum to the rectum of bovine animals of all ages, and ingredients derived therefrom;  ii) Skull, including the brain and spinal cord of ovine and caprine animals aged over 12 months or that have a permanent incisor tooth erupted through the gum, the spleens of ovine and caprine animals of all ages, and ingredients derived therefrom.  However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:  * Transesterification or hydrolysis at at least 200°C at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters) * Saponification with NaOH 12M (glycerol and soap): batch process: at 95°C for 3 hours <b>OR</b> continuous process: at 140°C, 2 bars (2000 hPa) for 8 minutes or equivalent conditions	-	419
643	Sodium cyanide	(388, 390, 409)	111
644	Sodium hexacyclonate (INN)	396	114
645	Sodium nitroferrocyanide	(15), 646	255
646	Sodium nitroprusside	(15), 645	255
647	<i>Solanum nigrum</i> L. and its galenical preparations	-	298
648	Spanish Fly	141	69
649	Sparteine (INN) and its salts	433	299
650	Spironolactone (INN)	10	4
651	Squill and its preparations	751	330
652	Stramonium and its preparations	232	301
653	Strontium lactate	-	402
654	Strontium nitrate	-	403

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
655	Strontium polycarboxylate	-	404
656	Strophantines and their aglucones and their respective derivatives	-	302
657	<i>Strophanthus</i> species and their galenical preparations	-	303
658	Strychnine and its salts	-	304
659	<i>Strychnos</i> species and their galenical preparations	521	305
660	Succinonitrile	-	150
661	Succinylsulphathiazole and its salts	(676)	307
662	Sulfinpyrazone (INN)	303	155
662a	3,3'-(Sulfonylbis(2-nitro-4,1-phenylene)imino)bis(6-(phenylamino)) benzenesulfonic acid and its salts, when used as a substance in hair dye products		1258
663	Sulphacetamide and its salts	(676)	307
664	Sulphadiazine and its salts	(676)	307
665	Sulphadimethoxine and its salts	(676)	307
666	Sulphadimidine and its salts	(676)	307
667	Sulphafurazole and its salts	(676)	307
668	Sulphaguanidine and its salts	(676)	307
669	Sulphamethizole and its salts	(676)	307
670	Sulphamethoxazole and its salts	(676)	307
671	Sulphamethoxydiazine and its salts	(676)	307
672	Sulphamethoxypyridazine and its salts	(676)	307
673	Sulphanilamide and its salts	(676)	307
674	Sulphapyridine and its salts	(676)	307
675	Sulphathiazole and its salts	(676)	307
676	Sulphonamides (Sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the NH <sub>2</sub> -groups) and and their salts	585, 661, 663 - 675	307
677	Sulthiame	678, 697	308

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
678	Sultiame (INN)	677, 697	308
679	Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical subscription and are referred to in resolution AP (69) 2 of the Council of Europe	44	21
680	Tefazoline (INN) and its salts	696	237
681	Tellurium and its compounds	-	312
682	TEPP (ISO)	694	276
683	2-(4-tert-Butyl-2,6-dimethylbenzyl)-2-imidazoline and its salts	765	313
684	4-tert Butylphenol	-	340
685	4-tert Butylpyrocatechol	-	341
686	Tetrabenazine (INN) and its salts	530	139
687	Tetrabromosalicylanilides	-	350
688	Tetracaine (INN) and its salts	280	63
689	2,3,7,8-Tetrachlorodibenzo-p-dioxin	-	367
690	Tetrachloroethylene	547	314
691	Tetrachloromethane	149	315
692	Tetrachlorosalicylanilides	-	348
693	Tetraethylammonium bromide	701	61
694	Tetraethyl pyrophosphate	682	276
695	5,6,6a,7-Tetrahydro-6-methyl-4H-dibenzo[de,g]quinoline-10,11-dihydric alcohol and its salts	59	42
696	2-(5,6,7,8-Tetrahydro-1-naphthylmethyl)-2-imidazoline and its salts	680	237
697	4-(Tetrahydro-2H-1,2-thiazin-2-yl)-benzenesulphonamide S,S-dioxide	677, 678	308
697a	Tetrahydro-6-nitroquinoxaline and its salts		1240
698	Tetrahydrozoline and its salts	-	394

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
698a	2',4',5',7'-Tetraiodofluorescein (CAS 15905-32-5; EINECS 240-046-0), its disodium salt (Acid Red 51; CI 45430) (CAS 16423-68-0; EINECS 240-474-8) and its aluminium salt (Pigment Red 172 Aluminium lake) (CAS 12227-78-0; EINECS 235-440-4 when used as a substance in hair dye products		1337
698b	1,1,4,4-Tetramethyl-6-ethyl-7-acetyl-1,2,3,4-tetrahydro-naphthalene	9, 342	362
699	N,2,3,3-Tetramethyl-2-norcamphanamine	438	229
700	Tetramethylthiuram disulphide	711	162
700a	Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonato phenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate (Food Black 2; CI 27755) (CAS 2118-39-0; EINECS 218-326-9) when used as a substance in hair dye products.		1354
701	Tetrylammonium bromide (INN)	693	61
702	Thalidomide (INN) and its salts	584	280
703	Thallium and its compounds	-	317
704	<i>Thevetia neriifolia</i> Juss. glycoside extract	-	318
705	Thiamazole (INN)	473, 475	233
706	2,2'-Thiobis(4,6-dichlorophenol)	116	352
707	Thiopentone and its salts	(70)	220
708	Thioridazine (INN) and its salts	(559)	320
709	Thiotepa (INN)	724	310
710	Thiourea and its derivatives (except those listed in Part 1 of Annex II)	-	321
711	Thiram (ISO)	700	162
712	Thiuram disulphides	-	354
713	Thiuram monosulphides	-	353
714	Thypropic acid (INN) and its salts	394	9
715	Tolboxane (INN)	718	177
716	Tolbutamide (INN)	135	65

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
716a	Toluene-3,4-Diamine (CAS 496-72-0) and its salts, when used as a substance in hair dye products		1313
717	Toluidines, their isomers, salts and halogenated and sulphonated derivatives	40	32
718	p-Tolylboric acid ester of 2-methyl-2-propylpropane-1,3-diol	715	177
719	3-o-Tolyloxypropane-1,2-diol	(440)	322
719a	<i>trans</i> -2-Heptenal (CAS No. 18829-55-5) when used as a fragrance ingredient	-	437
719b	<i>trans</i> -2-Hexenal diethyl acetal (CAS No. 67746-30-9) when used as a fragrance ingredient	-	438
719c	<i>trans</i> -2-Hexenal dimethyl acetal (CAS No. 18318-83-7) when used as a fragrance ingredient	-	439
720	Tranylcypromine (INN) and its salts	569	324
721	Tretamine (INN)	725	328
722	Tretinoin (INN) and its salts	635, 759	375
723	Triamterene (INN) and its salts	579	275
724	Tri(aziridin-1-yl)phosphine sulphide	709	310
725	2,4,6-Tri(aziridin-1-yl)-1,3-triazine	721	328
726	2,2,2-Tribromoethanol	(727)	326
727	Tribromoethyl alcohol	726	326
728	Tribromsalan (INN)	729	373
729	3,4',5-Tribromosalicylanilide	728	373
730	Trichlormethine (INN) and its salts	747	327
731	Trichloroacetic acid	-	10
732	1,1,1-Trichloro-2,-2-bis(4-chlorophenyl)ethane	196, 233	123
733	2,2,2-Trichloroethane-1,1-diol	159	77
734	Trichloromethane	169	366
735	N-(Trichloromethylthio) -4 - cyclohexene-1,2-dicarboximide	143	370
736	Trichloronitromethane	179	325

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
737	Tricresyl phosphate	748	277
738	Trifluoperazine (INN) and its salts	(559)	320
739	Trifluoperidol (INN)	349	188
739a	1,3,5-Trihydroxybenzene (CAS No 108-73-6) (Phloroglucinol) and its salts, when used as a substance in hair dye products		1253
740	3,3',5-Triiodothyroacetic acid and its salts	393	5
741	3,4,5-Trimethoxyphenethylamine and its salts	443	222
742	2,2,6-Trimethyl-4-piperidyl benzoate and its salts	76	51
742a	3,6,10-Trimethyl-3,5,9-undecatrien-2-one (CAS No. 1117-41-5) when used as a fragrance ingredient	-	449
743	2,4,6-Trinitrophenol	589	268
744	Trioxysalen (INN) (except natural content of essences) In sun protection and in bronzing products, furocoumarins content shall be below 1mg/kg	(357)	358
745	Triparanol (INN)	173	92
746	Tripelennamine (INN)	98, 624	347
747	Tris (2-chloroethyl)amine	730	327
747a	Trisodium 8-hydroxypyrene-1,3,6-trisulphonate (Solvent Green 7; CI 59040) (CAS 6358-69-6; EINECS 228-783-6) when used as a substance in hair dye products		1362
747b	Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate (Acid Red 27; CI 16185) (CAS 915-67-3; EINECS 213-022-2) when used as a substance in hair dye products		1350
747c	Trisodium tris[5,6-dihydro-5-(hydroxyimino-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-) (Acid Green 1; CI 10020) (CAS 19381-50-1; EINECS 243-010-2) when used as a substance in hair dye products		1342
748	Tritolyl phosphate	737	277
749	Tuaminoheptane (INN), its isomers and its salts	30	27

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
750	Thyrothricine (INN)	-	392
751	<i>Urginea scilla</i> Stern and its galenical preparations	651	330
752	Urocanic acid	(406)	418
753	Vaccines, toxins or serums listed in the Annex to the second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No L 147,9.6.1975, p.13) (OJ No. L 147, 9.6.1975, p. 13)	-	323
754	Valnoctamide (INN)	339	184
755	Veratrine, its salts and galenical preparations	-	331
756	<i>Veratrum spp</i> and their preparations	-	333
756a	Verbena essential oils ( <i>Lippia citriodora</i> Kunth.) and derivatives other than absolute (CAS No. 8024-12-2)when used as a fragrance ingredient		450
757	Vinyl Chloride monomer	-	334
758	Vinylidene chloride	(7, 250)	126
759	Vitamin A acid and its salts	635, 722	375
760	Vitamins D2 and D3	140, 188, 317	335
761	Warfarin (ISO) and its salts	3, 399	203
762	Xanthates	16	336
763	Xanthinol	392	135
763a	Xanthylum, 9-(2-carboxyphenyl)-3-(2-methylphenyl)amino)-6-((2-methyl-4-sulfophenyl)amino)-, inner salt (CAS 10213-95-3); and its sodium salt (Acid Violet 9; CI 45190) (CAS 6252-76-2; EINECS 228-377-9 when used as a substance in hair dye products		1335
764	Xylidines, their isomers, salts and halogenated and sulphonated derivatives	41	33
765	Xylometazoline (INN) and its salts	683	313
766	Yohimbine and its salts	-	337

(1) Number in this Annex	(2) Name of Substance	(3) Cross-reference to this Annex	(4) Cross-reference to Annex II of the original EU Directive
767	Zirconium and its compounds, with the exception of the complexes under reference no. 50 in Annex III, Part 1 and of zirconium lakes, salts and pigments of colouring agents listed with reference no. 3 in Annex IV	-	391
768	Zoxazolamine (INN)	28	24

In this Annex, names followed by (INN) are those published in "Computer print-out 1975, International non-proprietary names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

## ANNEX III - PART 1

### LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN, EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

#### Key

(<sup>1</sup>) As a preservative, see Annex VI, No 3

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

(<sup>3</sup>) As a preservative, see Annex VI, No 9

(<sup>4</sup>) As a preservative, see Annex VI, No 23

(<sup>5</sup>) As a preservative, see Annex VI, No 8

(\*) As preservative, see Annex VI, Part 1, No 34

(\*\*) This limit applies to the substance and not to the finished cosmetic product

(\*\*\*) The sum of those substances used in combination should not exceed the limits given in column 4

(\*\*\*\*) For use as a preservative, see Annex VI, Part 1, No 58

**26-Allergens: See pages 22-28**

**List of restricted fragrances or aromas used in cosmetic products :See pages 29-43 (IFRA)**

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
23	(a) Alkali sulphides  (b) Alkaline earth sulphides	(a) Depilatories  (b) Depilatories	(a) 2% calculated as sulphur pH up to 12,7  (b) 6% calculated as sulphur pH up to 12,7		(a) Keep out of reach of children Avoid contact with eyes  (b) Keep out of reach of children Avoid contact with eyes

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Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
4	Ammonia		6% calculated as NH <sub>3</sub>		Above 2%: Contains ammonia
94	Benzoyl peroxide	Artificial nail systems	0,7% (after mixing)	Professional use only	For professional use only Avoid skin contact Read directions for use carefully

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
1a	Boric acid, borates and tetraborates	<p>(a) Talcs</p> <p>(b) Products for oral hygiene</p> <p>(c) Other products (excluding bath products and hair waving products)</p>	<p>(a) 5% (by mass/mass as boric acid)</p> <p>(b) 0.1% (by mass/mass as boric acid)</p> <p>(c) 3% (by mass/mass as boric acid)</p>	<p>(a) Not to be used in products for children under three years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borate exceeds 1.5% (by mass/mass as boric acid)</p> <p>(b) 1. Not to be used in products for children under three years of age</p> <p>(c) 1. Not to be used in products for children under three years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borate exceeds 1.5% (by mass/mass as boric acid)</p>	<p>(a) 1. Not to be used in products for children under three years of age</p> <p>2. Not to be used on peeling or irritated skin</p> <p>(b) 1. Not to be swallowed</p> <p>2. Not to be used in products for children under three years of age</p> <p>(c) 1. Not to be used in products for children under three years of age</p> <p>2. Not to be used on peeling or irritated skin</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
1b	Tetraborates	(a) Bath Products  (b) Hair waving products	(a) 18% (by mass/mass as boric acid)  (b) 8% (by mass/mass as boric acid)	(a) Not to be used in products for children under three years of age	(a) Not to be used for bathing children under three years of age  (b) Rinse well
65	Benzalkonium chloride, bromide and saccharinate	(a) Rinse-off hair (head) care products  (b) Other products	(a) 3% (as benzalkonium chloride)  (b) 0.1% (as benzalkonium chloride)	(a) In the final product the concentration of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C14 or less must not exceed 0.1% (as benzalkonium chloride)	(a) Avoid contact with the eyes  (b) Avoid contact with the eyes
44	1,3-Bis(hydroxymethyl)imidazoline-2-thione	(a) Hair care preparations  (b) Nail care preparations	(a) Up to 2%  (b) Up to 2%	(a) Prohibited in aerosol dispensers (sprays)  (b) The pH of the product as applied must be less than 4	Contains 1,3-Bis(hydroxymethyl)imidazoline-2-thione

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
187	Butoxydiglycol CAS No 112-34-5 EC No 203-961-6  diethylene glycol monobutyl ether (DEGBE)	Solvent in hair dye products	9%	No use in aerosol dispensers (sprays)	
188	Butoxyethanol CAS 111-76-2 EC No 203-905-0  ethylene glycol monobutyl ether (EGBE)	Solvent in oxidative hair dye products  Solvent in non-oxidative hair dye products	4%  2%	No use in aerosol dispensers (sprays)  No use in aerosol dispensers (sprays)	
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt  (b) pH adjuster - for depilatories  (c) Other uses (e.g. pH adjuster, processing aid)	(a) 7% by weight calcium hydroxide	(b) pH value not to exceed pH 12.7  (c) pH value not to exceed pH 11	(a) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of the reach of children.  (b) Contains alkali. Avoid contact with eyes. Keep out of the reach of children.

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
6	Chlorates of alkali metals	(a) Other uses (b) Toothpaste	(a) 3% (b) 5%		
93	2,4-Diamino-pyrimidine-3-oxide (CAS No. 90028-67-4)	Hair care formulations	1,5%		
7	Dichloromethane		35% (when mixed with 1,1,1-trichloroethane total concentration not to exceed 35%)	0.2% as maximum impurity content	
11	Dichlorophen		0.5%		Contains dichlorophen
186	Diethylene Glycol (DEG) CAS No 111-46-6 EC No 203-872-2  2,2'-oxydiethanol	Traces in Ingredients	0.10%		
207	Ethyl Lauroyl Arginate HCl (INCI) (****)  Ethyl-N <sup>d</sup> -dodecanoyl-L-arginate hydrochloride CAS No 60372-77-2 EC No 434-630-6	(a) Soap (b) Anti-dandruff shampoos  c) Deodorants, not in form of spray	0.80%	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
53	Etidronic acid and its salts (1-Hydroxy-ethylidene-diphosphonic acid and its salts)	(a) Hair care  (b) Soap	(a) 1.5% expressed as etidronic acid  (b) 0.2% expressed as etidronic acid		
60	Fatty acid dialkylamides and dialkanolamides		Maximum secondary amine content: 0.5%	<ul style="list-style-type: none"> <li>- Do not use with nitrosating systems</li> <li>- Maximum secondary amine content: 5% (applies to raw materials)</li> <li>- Maximum nitrosamine content: 50µg/kg</li> <li>- Keep in nitrite-free containers</li> </ul>	
13	Formaldehyde	Nail hardeners	5% calculated as formaldehyde		Protect cuticles with grease or oil Contains formaldehyde (Only if the concentration exceeds 0.05%)
102	Glyoxal Glyoxal (INCI) CAS No 107-22-2 EINECS No 203-474-9		100 mg/kg		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair care preparations (b) Skin care preparations (c) Nail hardening preparations (d) Oral hygiene products	(a) 12% H <sub>2</sub> O <sub>2</sub> (40 volume) present or released (b) 4% H <sub>2</sub> O <sub>2</sub> present or released (c) 2% H <sub>2</sub> O <sub>2</sub> present or released (d) 0.1% H <sub>2</sub> O <sub>2</sub> present or released		(a) Wear suitable gloves  (a), (b), (c) Contains hydrogen peroxide Avoid contact with eyes Rinse eyes immediately if product comes into contact with them
99	Inorganic sulfites and bisulfites <sup>(3)</sup>	(a) Oxidative hair dye products (b) Hair straightening products (c) Self Tanning products for the face (d) Other self tanning products	(a) 0.67% expressed as free SO <sub>2</sub> (b) 6.7% expressed as free SO <sub>2</sub> (c) 0.45% expressed as free SO <sub>2</sub> (d) 0.40% expressed as free SO <sub>2</sub>	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	

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Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
9	<p>Methylphenylenediamines, their N-substituted derivatives and their salts <sup>(1)</sup>, with the exception of the substance under reference number 9a in this Annex and substances under reference numbers 478, 261b and 716a in Annex II</p> <p>(These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1)</p>	<p>Oxidising colouring agents for hair dyeing</p> <p>(a) General use</p> <p>(b) Professional use</p>	10% calculated as free base		<p>(a) Can cause an allergic reaction Contains phenylenediamines Do not use to dye eyelashes or eyebrows</p> <p>(b) For professional use only Contains phenylenediamines Can cause an allergic reaction Wear suitable gloves</p>
9a	<p>Toluene-2,5-diamine and its salts <sup>(1)</sup> CAS No 95-70-5 EINECS 202-442-1</p> <p>Toluene-2,5-diamine sulphate CAS No 615-50-9 EINECS 210-431-8</p>	<p>Hair dye substance in oxidative hair dye products</p> <p>(a) General use</p> <p>(b) Professional use</p>		<p>(a) and (b) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 4% calculated as free base</p>	<p>(a) Can cause an allergic reaction Contains phenylenediamines Do not use to dye eyelashes or eyebrows</p> <p>(b) For professional use only Contains phenylenediamines Can cause an allergic reaction Wear suitable gloves</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
61	Monoalkanolamines, monoalkanolamines and their salts		Maximum secondary amine content: 0.5%	<ul style="list-style-type: none"> <li>- Do not use with nitrosating systems</li> <li>- Minimum purity: 99%</li> <li>- Maximum secondary amine content: 0.5% (applies to raw materials)</li> <li>- Maximum N-nitrosodialkanolamine content: 50µg/kg</li> <li>- Keep in nitrite-free containers</li> </ul>	
97	Musk ketone (CAS No. 81-14-1)	All cosmetic products, with the exception of oral care products	(a) 1.4% in fine fragrance (b) 0.56% in eau de toilette (c) 0.042% in other products		
96	Musk xylene (CAS No. 81-15-2)	All cosmetic products, with the exception of oral care products	(a) 1.0% in fine fragrance (b) 0.4% in eau de toilette (c) 0.03% in other products		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
16	1-Naphthol (CAS No. 90-15-3) and its salts	Oxidising colouring agents for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction
18	Nitromethane	Rust inhibitor	0.3%		
3	Oxalic acid, its esters and alkaline salts	Hair care products	5%		For professional use only
54	1-Phenoxypropan-2-ol	Rinse-off products only Prohibited in oral hygiene products	2%	As preservative, see Annex VI Part 1, No. 43 - EU Directive reference number	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
8	<p>N-substituted derivatives of p-Phenylenediamine and their salts; N-substituted derivatives of o-Phenylenediamine <sup>(5)</sup>, with the exception of those derivatives listed elsewhere in this Annex and under reference numbers 243c,264a and 289b in Annex II.</p> <p>(These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1)</p>	<p>Oxidising colouring agents for hair dyeing</p> <p>(a) General use</p> <p>(b) Professional use</p>	6% calculated as free base		<p>(a) Can cause an allergic reaction Contains phenylenediamines Do not use to dye eyelashes or eyebrows</p> <p>(b) For professional use only Contains phenylenediamines Can cause an allergic reaction Wear suitable gloves</p>
8a	<p>p-Phenylenediamine and its salts <sup>(5)</sup> CAS No 106-50-3 EINECS 203-404-7</p> <p>p-Phenylenediamine HCl CAS No 624-18-0 EINECS 210-834-9</p> <p>p-Phenylenediamine sulphate CAS No 16245-77-5 EINECS 240-357-1</p>	<p>Hair dye substance in oxidative hair dye products</p> <p>(a) General use</p> <p>(b) Professional use</p>		<p>(a) and (b) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2% calculated as free base</p>	<p>(a) Can cause allergic reaction Contains phenylenediamines Do not use to dye eyelashes or eyebrows</p> <p>(b) For professional use only Contains phenylenediamines Can cause allergic reaction Wear suitable gloves</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
66	Polyacrylamides	(a) Body care leave-on products  (b) Other cosmetic products		(a) Maximum residual Acrylamide content 0.1 mg/kg  (b) Maximum residual Acrylamide content 0.5 mg/kg	
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent  (b) Hair straightener 1. General use  2. Professional use  (c) pH adjuster - depilatories  (d) Other uses as pH adjuster	(a) 5% by weight  (b) 1. 2% by weight  2. 4,5% by weight  (c) Up to pH 12.7  (d) Up to pH 11	(a) (b) The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide  In cases of mixtures, the sum total should not exceed the limits given in column 4	(a) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children  (b) 1. Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children  2. Professional use only Avoid contact with eyes Can cause blindness  (c) Avoid contact with eyes Keep out of reach of children

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
21	Quinine and its salts	(a) Shampoo  (b) Hair lotions	(a) 0.5% calculated as quinine base  (b) 0.2% calculated as quinine base		
51	Quinolin-8-ol and bis(8-hydroxyquinolinium)sulphate	(a) Stabiliser for hydrogen peroxide in rinse-off hair care preparations  (b) Stabiliser for hydrogen peroxide in non rinse-off hair care preparations	(a) 0.3% calculated as base  (b) 0.03% calculated as base		
22	Resorcinol  (These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1)	(a) Oxidising colouring agents for hair dyeing  1. General use   2. Professional use   (b) Hair lotions and shampoo	(a) 5%         (b) 0.5%		(a)  1. Contains resorcinol Rinse hair well after application Do not use to dye eyelashes or eyebrows Rinse eyes immediately if product comes into contact with them  2. For professional use only Contains resorcinol Rinse eyes immediately if product comes into contact with them  (b) Contains resorcinol

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
98	Salicylic Acid <sup>(1)</sup> (CAS No 69-72-7)	(a) Rinse-off hair products  (b) Other products  (c) Leave-on skin care products	(a) 3%  (b) 2%  (c) Max 2% pH min 3.5	Not to be used in preparations for children under three years of age, except for shampoos.  For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	(a), (b) & (c) Not to be used for children under three years of age <sup>(2)</sup>  (c) Above 0.5%, Sun Alert statement to appear on product label.  <b>Sun Alert</b> - Because this product may make your skin more sensitive to the sun, be certain that you apply a broad spectrum sunscreen of at least SPF 15 while using this product, and for a week after you discontinue use.
49	Selenium disulphide	Anti-dandruff shampoo	1%		Contains selenium disulphide Avoid contact with eyes or damaged skin
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4%		Contains silver nitrate Rinse eyes immediately if product comes into contact with them

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		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
17	Sodium nitrite	Rust inhibitor	0.2%	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
63	Strontium hydroxide	pH regulator in depilatory products	3.5% calculated as strontium, max pH of 12.7		Keep out of the reach of children Avoid contact with eyes
64	Strontium peroxide	Rinse-off hair care preparations for professional use	4.5% calculated as strontium in the ready-for-use preparations	All products to meet the hydrogen peroxide release requirements	Avoid contact with eyes Rinse eyes immediately if product comes into contact with them For professional use only Wear suitable gloves
59	Talc: Hydrated magnesium silicate	(a) Powdery products intended to be used for children under three years of age  (b) Other products			(a) Keep powder away from children's nose and mouth

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products - General use - Professional use (b) Depilatories (c) Other hair care products which are removed after application	- 8% ready for use pH 7.0 - 9.5 - 11% ready for use pH 7.0 - 9.5 - 5% ready for use pH 7.0 - 12.7 - 2% ready for use pH 7.0 - 9.5 Percentages calculated as thioglycolic acid	(a) (b) (c) The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: - Avoid contact with eyes - In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice. - Wear suitable gloves [(a) and (c) only]	(a) Contains thioglycolate Follow the instructions Keep out of reach of children - For professional use only (b) and (c) Contains thioglycolate Follow the instructions Keep out of reach of children
2b	Thioglycolic acid esters	Hair waving or straightening products - General use - Professional use	- 8% ready for use pH 6.0 - 9.5 - 11% ready for use pH 6.0 - 9.5 Percentages calculated as thioglycolic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: - May cause sensitisation in the event of skin contact - Avoid contact with eyes - In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice - Wear suitable gloves	- Contains thioglycolate - Follow the instructions - Keep out of reach of children - For professional use only

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
185	Toluene CAS No 108-88-3 EC No 203-625-9	Nail Products	25%		Keep out of reach of children To be used by adults only
5	Tosylchloramide sodium		0.2%		
62	Trialkylamines, trialkanolamines and their salts	(a) Non rinse-off products  (b) Other products	(a) 2.5%	(a) (b) - Do not use with nitrosating systems - Minimum purity 99% - Maximum secondary amine content: 0.5% (concerns raw materials) - Maximum N-nitrosodialkanolamine content: 50µg/kg - Keep in nitrite-free containers	
100	Triclocarban <sup>(4)</sup> (CAS No 101-20-2)	Rinse-off products	1.50%	Purity Criteria:  3,3',4,4'-Tetrachloroazobenzene ≤ 1 ppm  3,3',4,4'-Tetrachloroazoxybenzene ≤ 1 ppm  For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	

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Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
206	Verbena absolute ( <i>Lippia citriodora</i> Kunth.) CAS No 8024-12-2		0.20%		
24	Water-soluble zinc salts with the exception of zinc-4-hydroxy-benzenesulphonate and zinc pyrithione		1% calculated as zinc		
25	Zinc-4-hydroxybenzene sulphonate	Deodorants, antiperspirants and astringent lotions	6% calculated as % of anhydrous substance		Avoid contact with eyes
101	Zinc pyrithione <sup>(5)</sup> (CAS No 13463-41-7)	Leave-on hair products	0.10%	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
67	Amyl Cinnamal (CAS No 122-40-7)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
45	Benzyl Alcohol (*) (CAS No 100-51-6)	(a) Solvent  (b) Fragrance/aromatic compositions/their raw materials		(b) The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
69	Cinnamyl Alcohol (CAS No 104-54-1)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
70	Citral (CAS No 5392-40-5)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	

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		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
71	Eugenol (CAS No 97-53-0)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
72	Hydroxycitronellal (CAS No 107-75-5)	(a) Oral Products  (b) Other products	(b) 1%	(a) and (b) The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
73	Isoeugenol (CAS No 97-54-1)	(a) Oral Products  (b) Other Products	(b) 0.02%	(a) and (b) The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
74	Amylcinnamyl Alcohol (CAS No 101-85-9)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
75	Benzyl Salicylate (CAS No 118-58-1)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
76	Cinnamal (CAS No 104-55-2)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
77	Coumarin (CAS No 91-64-5)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
78	Geraniol (CAS No 106-24-1)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
79	Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (CAS No 31906-04-4)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
80	Anise Alcohol (CAS No 105-13-5)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
81	Benzyl Cinnamate (CAS No 103-41-3)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
82	Farnesol (CAS No 4602-84-0)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	

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Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
83	Butylphenyl Methylpropional (CAS No 80-54-6)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
84	Linalool (CAS No 78-70-6)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
85	Benzyl Benzoate (CAS No 120-51-4)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
86	Citronellol (CAS No 106-22-9)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
87	Hexyl Cinnamal (CAS No 101-86-0)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
88	<i>d</i> -Limonene (CAS No 5989-27-5)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products  Peroxide value less than 20mmoles/L (**)	
89	Methyl 2-octynoate (CAS No 111-12-6)  Methyl heptine carbonate	(a) Oral products  (b) Other products	(b) 0.01% when used alone  When present in combination with methyl octine carbonate, the combined level in the finished product should not exceed 0.01% (of which methyl octine carbonate should not be more than 0,002%	(a) and (b) The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	

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		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
90	Alpha-Isomethyl Ionone (CAS No 127-51-5)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
91	Evernia Prunastri (CAS No 90028-68-5)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	
92	Evernia Furfuracea (CAS No 90028-67-5)			The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: - 0,001% in leave-on products - 0,01% in rinse-off products	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
103	Abies alba cone oil and extract CAS No 90028-76-5			Peroxide value less than 10 mmoles/L(**)	
104	Abies alba needle oil and extract CAS No 90028-76-5			Peroxide value less than 10 mmoles/L(**)	
105	Abies pectinata needle oil and extract CAS No 92128-34-2			Peroxide value less than 10 mmoles/L(**)	
106	Abies sibirica needle oil and extract CAS No 91697-89-1			Peroxide value less than 10 mmoles/L(**)	
107	Abies balsamea needle oil and extract CAS No 85085-34-3			Peroxide value less than 10 mmoles/L(**)	
108	Pinus mugo pumilio leaf and twig oil and extract CAS No 90082-73-8			Peroxide value less than 10 mmoles/L(**)	
109	Pinus mugo leaf and twig oil and extract CAS No 90082-72-7			Peroxide value less than 10mmoles/L(**)	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
110	Pinus sylvestris leaf and twig oil and extract CAS No 84012-35-1			Peroxide value less than 10mmoles/L(**)	
111	Pinus nigra leaf and twig oil and extract CAS No 90082-74-9			Peroxide value less than 10mmoles/L(**)	
112	Pinus palustris leaf and twig oil and extract CAS No 97435-14-8			Peroxide value less than 10mmoles/L(**)	
113	Pinus pinaster leaf and twig oil and extract CAS No 90082-75-0			Peroxide value less than 10mmoles/L(**)	
114	Pinus pumila leaf and twig oil and extract CAS No 97676-05-6			Peroxide value less than 10mmoles/L(**)	
115	Pinus species leaf and twig oil and extract CAS No 94266-48-5			Peroxide value less than 10mmoles/L(**)	
116	Pinus cembra leaf and twig oil and extract CAS No 92202-04-5			Peroxide value less than 10mmoles/L(**)	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
117	Pinus cembra leaf and twig extract acetylated CAS No 94334-26-6			Peroxide value less than 10mmoles/L(**)	
118	Picea Mariana Leaf Oil and Extract CAS No 91722-19-9			Peroxide value less than 10mmoles/L(**)	
119	Thuja Occidentalis Leaf Oil and Extract CAS No 90131-58-1			Peroxide value less than 10mmoles/L(**)	
120	Thuja Occidentalis Stem Oil CAS No 90131-58-1			Peroxide value less than 10mmoles/L(**)	
121	3-Carene CAS No 13466-78-9  3,7,7-Trimethyl-bicyclo[4.1.0]hept-3-ene (isodiprene)			Peroxide value less than 10mmoles/L(**)	
122	Cedrus atlantica wood oil and extract CAS No 92201-55-3			Peroxide value less than 10mmoles/L(**)	
123	Cupressus sempervirens leaf oil and extract CAS 84696-07-1			Peroxide value less than 10mmoles/L(**)	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
124	Turpentine gum ( <i>Pinus</i> supp.) CAS No 9005-90-7			Peroxide value less than 10mmoles/L(**)	
125	Turpentine oil and rectified oil CAS 8006-64-2			Peroxide value less than 10mmoles/L(**)	
126	Turpentine, steam distilled ( <i>Pinus</i> supp.) CAS No 8006-64-2			Peroxide value less than 10mmoles/L(**)	
127	Terpene alcohols acetates CAS No 69103-01-1			Peroxide value less than 10mmoles/L(**)	
128	Terpene hydrocarbons CAS No 68956-56-9			Peroxide value less than 10mmoles/L(**)	
129	Terpenes and terpenoids with the exception of limonene (d-,l-, and dl-isomers) listed under reference numbers 167, 168 and 88 of this Annex III, part 1 CAS 65996-98-7			Peroxide value less than 10mmoles/L(**)	
130	Terpenes and terpenoids CAS No 68917-63-5			Peroxide value less than 10mmoles/L(**)	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
131	$\alpha$ -Terpinene CAS No 99-86-5 p-Mentha-1,3-diene			Peroxide value less than 10mmoles/L(**)	
132	$\gamma$ -Terpine CAS No 99-85-4 p-Mentha-1,4-diene			Peroxide value less than 10mmoles/L(**)	
133	Terpinolene CAS No 586-62-9 p-Mentha-1,4(8)-diene			Peroxide value less than 10mmoles/L(**)	
134	Acetyl hexamethyl indan CAS No 15323-35-0 1,1,2,3,3,6-Hexamethylindan-5-yl methyl ketone	(a) Leave-on products  (b) Rinse-off products	(a) 2%		
135	Allyl butyrate CAS No 2051-78-7 2-Propenyl Butanoate			Level of free allyl alcohol in the ester should be less than 0,1%	
136	Allyl cinnamate CAS No 1866-31-5 2-Propenyl 3-Phenyl-2-propenoate			Level of free allyl alcohol in the ester should be less than 0,1%	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
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Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
137	Allyl cyclohexylacetate CAS No 4728-82-9 2-Propenyl Cyclohexaneacetate			Level of free allyl alcohol in the ester should be less than 0,1%	
138	Allyl cyclohexylpropionate CAS No 2705-87-5 2-Propenyl 3-Cyclohexane-propanoate			Level of free allyl alcohol in the ester should be less than 0,1%	
139	Allyl heptanoate CAS No 142-19-8 2-Propenyl heptanoate			Level of free allyl alcohol in the ester should be less than 0,1%	
140	Allyl caproate CAS 123-68-2 Allyl hexanoate			Level of free allyl alcohol in the ester should be less than 0,1%	
141	Allyl isovalerate CAS No 2835-39-4 2-Propenyl 3-Methyl-butanoate			Level of free allyl alcohol in the ester should be less than 0,1%	
142	Allyl octanoate CAS No 4230-97-1 2-Allyl caprylate			Level of free allyl alcohol in the ester should be less than 0,1%	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
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Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
143	Allyl phenoxyacetate CAS No 7493-74-5 2-Propenyl Phenoxyacetate			Level of free allyl alcohol in the ester should be less than 0,1%	
144	Allyl phenylacetate CAS No 1797-74-6 2-Propenyl Benzeneacetate			Level of free allyl alcohol in the ester should be less than 0,1%	
145	Allyl 3,5,5-trimethylhexanoate CAS No 71500-37-3			Level of free allyl alcohol in the ester should be less than 0,1%	
146	Allyl cyclohexyloxyacetate CAS No 68901-15-5			Level of free allyl alcohol in the ester should be less than 0,1%	
147	Allyl isoamyloxyacetate CAS No 67634-00-8			Level of free allyl alcohol in the ester should be less than 0,1%	
148	Allyl 2-methylbutoxyacetate CAS No 67634-01-9			Level of free allyl alcohol in the ester should be less than 0,1%	
149	Allyl nonanoate CAS No 7493-72-3			Level of free allyl alcohol in the ester should be less than 0,1%	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
150	Allyl propionate CAS No 2408-20-0			Level of free allyl alcohol in the ester should be less than 0,1%	
151	Allyl trimethylhexanoate CAS No 68132-80-9			Level of free allyl alcohol in the ester should be less than 0,1%	
151a	Allyl phenethyl ether CAS No 14289-65-7 EC No 238-212-2			Level of free allyl alcohol in the ester should be less than 0,1%	
152	Allyl heptine carbonate CAS No 73157-43-4 (allyl oct-2-ynoate)		0,002%	This material should not be used in combination with any other 2-alkynoic acid ester (e.g. methyl heptine carbonate)	
153	Amylcyclopentenone CAS No 25564-22-1 2-Pentylcyclopent-2-en-1-one		0.10%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
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Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
154	<i>Myroxylon balsamum</i> var <i>pereirae</i> extracts and <i>distillates</i> CAS No 8007-00-9 Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru)		0.40%		
155	4- <i>tert.</i> -Butyldihydro cinnamaldehyde CAS No 18127-01-0 3-(4- <i>tert</i> -Butylphenyl) propionaldehyde		0.60%		
156	Cuminum cyminum fruit oil and extract CAS No 84775-51-9	(a) Leave-on products (b) Rinse-off products	(a) 0.4% of Cumin oil		
157	<i>cis</i> -Rose ketone-1 (***) CAS No 23726-94-5 (Z)-1-(2,6,6-Trimethyl-2-cyclohexen-1yl)-2-buten-1-one ( <i>cis</i> - $\alpha$ -Damascone)	(a) Oral products (b) Other products	(b) 0.02%		
158	<i>trans</i> Rose ketone-2(***) CAS No 23726-91-2 (E)-1-(2,6,6-Trimethyl-1-cyclohexen-1yl)-2-buten-1-one ( <i>trans</i> - $\beta$ -Damascone)	(a) Oral products (b) Other products	(b) 0.02%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
159	<i>trans</i> Roseketone-5 (***) CAS No 39872-57-6 (E)-1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (Isodamascone)		0.02%		
160	Rose ketone-4 (***) CAS No 23696-85-7 1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one (Damasconone)	(a) Oral products (b) Other products	(b) 0.02%		
161	Rose ketone-3(***) CAS No 57378-68-4 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (Delta Damascone)	(a) Oral Products (b) Other products	(b) 0.02%		
162	<i>cis</i> -Rose ketone-2(***) CAS No 23726-92-3 1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one ( <i>cis</i> - $\beta$ -Damascone)	(a) Oral Products (b) Other products	(b) 0.02%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
163	<i>trans</i> -Rose ketone-1(***) CAS No 24720-09-0 1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one ( <i>trans</i> - $\alpha$ -Damascone)	(a) Oral Products (b) Other products	(b) 0.02%		
164	Rose ketone-5(***) CAS No 33673-71-1 1-(2,4,4-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one		0.02%		
165	<i>trans</i> -Rose ketone-3(***) CAS No 71048-82-3 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one ( <i>trans</i> -delta-Damascone)	(a) Oral Products (b) Other products	(b) 0.02%		
166	<i>trans</i> -2- hexenal CAS No 6728-26-3	(a) Oral Products (b) Other products	(b) 0,002%		
167	<i>l</i> -Limonene CAS No 5989-54-8 (S)- <i>p</i> -Mentha-1,8-diene			Peroxide value less than 20mmoles/L(**)	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
168	<i>d/l</i> -Limonene (racemic) CAS No 138-86-3 1,8(9)- <i>p</i> -Menthadiene; <i>p</i> -Mentha-1,8-diene (Dipentene)			Peroxide value less than 20mmoles/L(**)	
169	Perillaldehyde CAS No 2111-75-3 <i>p</i> -Mentha-1,8-dien-7-al	(a) Oral Products  (b) Other products	  (b) 0.10%		
170	Isobergamate CAS No 68683-20-5 Menthadiene-7-methylformate		0.10%		
171	Methoxy dicyclopentadiene carboxaldehyde CAS No 86803-90-9 Octahydro-5-methoxy-4,7-Methano 1H-indene-2-carboxaldehyde		0.50%		
172	3-methylnon-2-enenitrile CAS No 53153-66-5		0.20%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
173	Methyl octine carbonate CAS No 111-80-8 Methyl non-2-ynoate	(a) Oral products  (b) Other Products	(b) 0.002% when used alone When present in combination with methyl heptine carbonate, the combined level in the finished product should not exceed 0.01% (of which methyl octine carbonate should not be more than 0.002%)		
174	Amylvinylcarbiny acetate CAS No 2442-10-6 1-Octen-3-yl acetate	(a) Oral Products  (b) Other products	(b) 0.30%		
175	Propylidenephthalide CAS No 17369-59-4 3-Propylidenephthalide	(a) Oral Products  (b) Other products	(b) 0.01%		
176	Isocyclogeraniol CAS No 68527-77-5 2,4,6-Trimethyl-3-cyclohexene-1-methanol		0.50%		
177	2-Hexylidene cyclopentanone CAS No 17373-89-6	(a) Oral Products  (b) Other products	(b) 0.06%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
178	Methyl heptadienone CAS No 1604-28-0 6-Methyl-3,5-heptadien-2-one	(a) Oral Products (b) Other products	(b) 0,002%		
179	p-methylhydrocinnamic aldehyde CAS No 5406-12-2 Cresylpropionalde-hyde p-Methyldihydrocinnamaldehyde		0.20%		
180	Liquidambar orientalis Balsam oil and extract CAS No 94891-27-7 (styrax)		0.60%		
181	Liquidambar styraciflua balsam oil and extract CAS No 8046-19-3 (styrax)		0.60%		
182	Acetyl hexamethyl tetralin CAS No 21145-77-7 CAS No 1506-02-1 1-(5,6,7,8-Tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN)	All cosmetic products, with the exception of oral products	(a) leave on products: 0.1% except: hydro alcoholic products: 1% fine fragrance:2.5% fragrance cream:0,5%  (b) rinse off products: 0.2%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
183	<i>Commiphora erythrea</i> engler var. <i>glabrescens</i> engler gum extract and oil CAS No 93686-00-1		0.60%		
184	Opopanax chironium resin CAS No 93384-32-8		0.60%		

## ANNEX III - PART 2

### LIST OF SUBSTANCES WHICH COSMETIC ORAL HYGIENE PRODUCTS MUST NOT CONTAIN, EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
34	Aluminium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains aluminium fluoride  For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:  "Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
33	Ammonium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains ammonium fluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
42	Ammonium fluorosilicate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains ammonium fluorosilicate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
26	Ammonium monofluorophosphate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains ammonium monofluorophosphate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
30	Calcium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains calcium fluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>
	Calcium glycerophosphate	Oral hygiene products	0.06% - 0.2% m/m		Contains calcium glycerophosphate

**CONTINUES ON PAGE 130 - PART 2**

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
29	Calcium monofluorophosphate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains calcium monofluorophosphate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>
6	Chlorates of alkali metals	Toothpaste	Max 5% m/m		
	Disodium pyrophosphate	Oral hygiene products	Max 3.3% as soluble pyrophosphate		Contains disodium pyrophosphate

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
36	Hexadecyl ammonium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains hexadecyl ammonium fluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
37	3-(N-hexadecyl-N-2-hydroxyethyl ammonio)propylbis (2-hydroxyethyl)ammonium dihydrofluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains 3-(N-hexadecyl -N-2-hydroxyethyl ammonio)propylbis (2-hydroxyethyl) ammonium dihydrofluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>
12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	Oral hygiene products	0.1% of H <sub>2</sub> O <sub>2</sub> present or released		Contains hydrogen peroxide

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
15	Triclosan (INN)	Oral hygiene products	0,3%		Contains triclosan
56	Magnesium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains magnesium fluoride  For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:  "Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
43	Magnesium fluorosilicate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains magnesium fluorosilicate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>
46	6-Methylcoumarin	Oral hygiene products	0.003%		

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
47	Nicomethanol hydrofluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains nicomethanol hydrofluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
39	Octadecenyl-ammonium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains octadecenyl-ammonium fluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
32	Potassium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains potassium fluoride</p> <p>Contains octadecenyl-ammonium fluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
41	Potassium fluorosilicate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains Potassium fluorosilicate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
28	Potassium monofluorophosphate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains potassium monofluorophosphate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
31	Sodium fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains sodium fluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
40	Sodium fluorosilicate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains sodium fluorosilicate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
27	Sodium monofluorophosphate	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains sodium monofluorophosphate</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
35	Stannous fluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		Contains stannous fluoride  For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:  "Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor
58	Strontium acetate hemihydrate	Toothpaste	3.5% calculated as strontium When mixed with other permitted strontium products the total strontium content not to exceed 3.5%		Contains strontium acetate Frequent use by children is not advisable
57	Strontium chloride hexahydrate	Toothpaste	3.5% calculated as strontium When mixed with other permitted strontium products the total strontium content not to exceed 3.5%		Contains strontium chloride Frequent use by children is not advisable

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	Strontium salts	Oral hygiene products	3.0% - 5.0% m/m as strontium		Contains strontium salts
	Tetra potassium pyrophosphate	Oral hygiene products	Max 3.3% as soluble pyrophosphate		Contains tetrapotassium pyrophosphate
	Tetra sodium pyrophosphate	Oral hygiene products	Max 3.3% as soluble pyrophosphate		Contains tetrasodium pyrophosphate
38	N N' N"-tris(polyoxyethylene)-N-hexa-decylpropylenediamine dihydrofluoride	Oral hygiene products	0,15% calculated as fluoride ion. When mixed with other fluoride compounds permitted under this Annex, total fluoride ion concentration not to exceed 0.15% m/m.		<p>Contains N N' N"-tris (polyoxyethylene)-N-hexa-decylpropylene diaminedihydrofluoride</p> <p>For any toothpaste containing 0.1 to 0.15% fluoride unless it is already labelled as contra-indicated for children (e.g "for adult use only") the following labelling is obligatory:</p> <p>"Children of 6 years and younger: Use pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
24	Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzene-sulphonate and zinc pyrithione	Oral hygiene products	Max 1% m/m calculated as zinc		Contains water-soluble zinc salts with the exception of zinc 4-hydroxy-benzene-sulphonate and zinc pyrithione

## ANNEX III - PART 3

### LIST OF SUBSTANCES WHICH COSMETIC HAIR DYES MUST NOT CONTAIN, EXCEPT SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

**Note 1:** Refer to Reference Numbers 8, 9, 10, 16 and 22 in Annex III Part 1 for hair dyes not listed in Part 3

<sup>(15)</sup> The free base and salts of this hair colouring ingredient, unless prohibited under Annex II, are permitted for use.

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
56	2-Amino-6-chloro-4-nitrophenol (CAS No. 6358-09-4) and its salts	(a) Oxidising colouring agent for hair dyeing  (b) Non-oxidising colouring agent for hair dyeing	(a) 2.0%  (b) 2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	
19	3-Amino-2,4-dichlorophenol (CAS No. 61693-43-4) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
35	4-Amino-2-hydroxytoluene (CAS No. 2835-95-2) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
3	4-Amino-3-nitrophenol (CAS No. 610-81-1) and its salts	(a) Oxidising colouring agent for hair dyeing	(a) 3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	(a) (b) Can cause an allergic reaction
		(b) Non-oxidising colouring agent for hair dyeing	(b) 3.0%		
39	2-Amino-4-hydroxyethyl aminoanisoie (CAS No. 83763-47-7) and its salts	Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	

Reference Number	Substance		Restrictions				Conditions of use and warnings to be printed on the label		
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements				
Column 1	Column 2		Column 3	Column 4	Column 5		Column 6		
38		4-Amino-m-cresol (CAS No. 2835-99-6) and its salts		Oxidising colouring agent for hair dyeing		3.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
5		m-Aminophenol (CAS No. 591-27-5) and its salts		Oxidising colouring agent for hair dyeing		2.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction
34		o-Aminophenol (CAS No. 95-55-6) and its salts		Oxidising colouring agent for hair dyeing		2.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6
190	Benzenemethanaminium, N-ethyl-N-[4-[[4-[ethyl-[(3-sulfo-phenyl)-methyl]-amino]-phenyl]][2-sulfophenyl)-methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfo, inner salt, disodium salt and its ammonium and aluminium salts <sup>(15)</sup>  Acid Blue 9 CAS 3844-45-9 EINECS 223-339-8  Acid Blue 9 Ammonium salt CAS 2650-18-2 EINECS 220-168-0  Acid Blue 9 Aluminum lake CAS 68921-42-6 EINECS 272-939-6 CI 42090		Hair dye substance in non-oxidative hair dye product	0.50%		
18	1,3-Bis-(2,4-diamino-phenoxy) propane CAS No 81892-72-0		Oxidising colouring agent for hair dyeing		In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause allergic reaction

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label	
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements		
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6	
55	2-Chloro-6-ethylamino-4-nitrophenol CAS No. 131657-78-8 and its salts	(a)	Oxidising colouring agent for hair dyeing	(a) 3%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%		
36	2,4-Diaminophenoxyethanol (CAS No. 70643-19-5) and its salts		Oxidising colouring agent for hair dyeing	4.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 2.0%		
197	1,5-Di-( $\beta$ -hydroxyethylamino)-2-nitro-4-chlorobenzene <sup>(15)</sup>  HC Yellow No 10 CAS 109023-83-8 EINECS 416-940-3		Hair dye substance in non-oxidative hair dye products	0.10%	Do not use with nitrosating systems  Maximum nitrosamine content: 50 $\mu$ g/kg  Keep in nitrite-free containers		

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6
204	2,3-Dihydro-1H-indole-5,6-diol and its hydrobromide salt <sup>(15)</sup>  Dihydroxyindoline CAS 29539-03-5  Dihydroxyindolene HBr CAS 138937-28-7 EINECS 421-170-6		Hair dye substance in non-oxidative hair dye products	2%		Can cause allergic reaction
6	2,6-Dihydroxy-3,4-dimethyl pyridine (CAS No. 84540-47-6) and its salts		Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	Can cause an allergic reaction

Reference Number	Substance		Restrictions				Conditions of use and warnings to be printed on the label		
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements				
Column 1	Column 2		Column 3		Column 4		Column 5		Column 6
25		2,6-Dimethoxy-3,5-pyridine diamine (CAS No. 85679-78-3) and its salts		Oxidising colouring agent for hair dyeing		0.5%		In combination with hydrogen peroxide the maximum use concentration upon application is 0.25%	Can cause an allergic reaction
194		Disodium 5-amino-4-hydroxy-3-(phenylazo) naphthalene-2,7-disulphonate <sup>(15)</sup>  Acid Red 33 CAS 3567-66-6 EINECS 222-656-9 CI 17200		Hair dye substance in non-oxidative hair dye products		0.50%			
191		Disodium 6-hydroxy-5-[(2-methoxy 4-sulphonato-m-tolyl)azo] naphthalene-2-sulphonate <sup>(15)</sup>  Curry Red CAS 25956-17-6 EINECS 247-368-0 CI 16035		Hair dye substance in non-oxidative hair dye products		0.40%			

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
16	HC Blue No. 12 (CAS No. 104516-93-0) and its salts	(a) Oxidising colouring agent for hair dyeing  (b) Non-oxidising colouring agent for hair dyeing	(a) 1.5%  (b) 1.5%	In combination with hydrogen peroxide the maximum use concentration upon application is 0.75%	(a) (b) Can cause an allergic reaction
26	HC Orange No.2 (CAS No. 85765-48-6) and its salts	Non-oxidising colouring agent for hair dyeing	1.0%		
50	HC Red No. 10 (CAS No. 95576-89-9) and its salts AND HC Red No. 11 (CAS No. 95576-92-4) and its salts	(a) Oxidising colouring agent for hair dyeing  (b) Non-oxidising colouring agent for hair dyeing	(a) 2.0%  (b) 1.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
31	HC Red No. 13 (CAS No. 92705-39-3) and its salts	(a) Oxidising colouring agent for hair dyeing  (b) Non-oxidising colouring agent for hair dyeing	(a) 2.5%  (b) 2.5%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.25%	
27	HC Violet No.1 (CAS No. 82576-75-8) and its salts	(a) Oxidising colouring agent for hair dyeing  (b) Non-oxidising colouring agent for hair dyeing	(a) 0.5%  (b) 0.5%	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25%	

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6
193	Hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonato-phenyl) xanthylium, sodium salt <sup>(15)</sup>  Acid Red 52 CAS 3520-42-1 EINECS 222-529-8 CI 45100		(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 0.60%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5%	(a) Mixing ratio must be printed on the label.
22	Hydroxybenzomorpholine CAS No 26021-57-8 and its salts		Oxidising colouring agent for hair dyeing	2%	In combination with hydrogen peroxide the maximum use concentration upon application is 1%	Can cause allergic reaction
199	2,2'-[[4-[(2-hydroxyethyl)amino]-3-nitrophenyl]imino]bisethanol <sup>(15)</sup>  HC Blue No 2 CAS 33229-34-4 EINECS 251-410-3		Hair dye substance in non-oxidative hair dye products	2.80%	Do not use with nitrosating systems  Maximum nitrosamine content: 50 µg/kg Keep in nitrite-free containers	Can cause allergic reaction

Reference Number	Substance		Restrictions				Conditions of use and warnings to be printed on the label		
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements				
Column 1	Column 2		Column 3		Column 4		Column 5		Column 6
44		Hydroxyethyl-3,4-methylene dioxyaniline (CAS No. 81329-90-0) and its salts		Oxidising colouring agent for hair dyeing		3.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	
10		Hydroxyethyl-2-nitro-p-toluidine (CAS No. 100418-33-5) and its salts	(a)	Oxidising colouring agent for hair dyeing	(a)	2.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	(a) (b) Can cause an allergic reaction
			(b)	Non-oxidising colouring agent for hair dyeing	(b)	1.0%			
29		2-Hydroxy-ethylamino-5-nitro anisole (CAS No. 66095-81-6) and its salts		Non-oxidising colouring agent for hair dyeing		1.0%			

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6
11	2-Hydroxy-ethylpicramic acid (CAS No. 99610-72-7) and its salts	(a)	Oxidising colouring agent for hair dyeing	(a) 3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	(a) (b) Can cause an allergic reaction
		(b)	Non-oxidising colouring agent for hair dyeing	(b) 2.0%		
205	4-Hydroxypropylamino-3-nitro-phenol <sup>(15)</sup>  4-Hydroxypropylamino-3-nitro-phenol (INCI) CAS 92952-81-3 EINECS 406-305-9	(a)	Hair dye substance in oxidative hair dye products	(b) 2.60%	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.6% calculated as free base  For (a) and (b)  Do not use with nitrosating systems  Maximum nitrosamine content: 50 µg/kg  Keep in nitrite-free containers	(a) The mixing ratio must be printed on the label.
		(b)	Hair dye substance in non-oxidative hair dye products			

Reference Number	Substance		Restrictions				Conditions of use and warnings to be printed on the label			
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements					
Column 1	Column 2		Column 3		Column 4		Column 5	Column 6		
33		Hydroxypropyl bis(N-hydroxy ethyl-p-phenylenediamine) (CAS No. 128729-30-6) and its salts		Oxidising colouring agent for hair dyeing		3.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%		Can cause an allergic reaction
21		2-Methyl-5-hydroxyethyl aminophenol (CAS No. 55302-96-0) and its salts		Oxidising colouring agent for hair dyeing		2.0%		In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%		Can cause an allergic reaction
198		3-Methylamino-4-nitrophenoxy-ethanol <sup>(15)</sup>  3-Methylamino-4-nitrophenoxy-ethanol (INCI) CAS 59820-63-2 EINECS 261-940-7		Hair dye substance in non-oxidative hair dye products		0.15%		Do not use with nitrosating systems  Maxmum nitrosamine content:50 µg/kg  Keep in nitrite-free containers		

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6
12	p-Methylaminophenol (CAS No. 150-75-4) and its salts		Oxidising colouring agent for hair dyeing	3.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5%	Can cause an allergic reaction
196	1-[(2'-Methoxyethyl)amino]-2-nitro-4-[di-(2'-hydro-xyethyl)amino]benzene <sup>(15)</sup>  HC Blue No 11 CAS 23920-15-2 EINECS 459-980-7		Hair dye substance in non-oxidative hair dye products	2%	Do not use with nitrosating systems  Maximum nitrosamine content:50 µg/kg  Keep in nitrite-free containers	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
203	<p>6-Methoxy-N2-methyl-2,3-pyridine diamine hydrochloride and dihydro chloride salt <sup>(15)</sup></p> <p>6-Methoxy-2-methylamino-3-amino-pyridine HCl CAS 90817-34-8 (HCl) CAS 83732-72-3 (2HCl) EINECS 280-622-9 (2HCl)</p>	<p>(a) Hair dye substance in oxidative hair dye products</p> <p>(b) Hair dye substance in non-oxidative hair dye products</p>	<p>(b) 0.68% as free base (1% as dihydrochloride)</p>	<p>(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.68% calculated as free base (1% as dihydro chloride)</p> <p>For (a) and (b):</p> <p>Do not use with nitrosating systems</p> <p>Maximum nitrosamine content: 50 µg/kg</p> <p>Keep in nitrite-free containers</p>	<p>(a) The mixing ratio must be printed on the label</p> <p>For (a) and (b): Can cause allergic reaction</p>
37	2-Methylresorcinol (CAS No. 608-25-3) and its salts	Oxidising colouring agent for hair dyeing	2.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%	

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label	
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements		
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6	
32		1,5-Naphthalenediol (CAS No. 83-56-7) and its salts		Oxidising colouring agent for hair dyeing		1.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5%
4		2,7-Naphthalenediol (CAS No. 582-17-2) and its salts		Oxidising colouring agent for hair dyeing		1.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5%
48		3-Nitro-p-hydroxyethylamino phenol (CAS No. 65235-31-6) and its salts	(a)	Oxidising colouring agent for hair dyeing	(a)	6.0%	In combination with hydrogen peroxide the maximum use concentration upon application is 3.0%
			(b)	Non-oxidising colouring agent for hair dyeing	(b)	6.0%	

Reference Number	Substance		Restrictions			Conditions of use and warnings to be printed on the label
			Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2		Column 3	Column 4	Column 5	Column 6
49	4-Nitrophenylaminoethylurea (CAS No. 27080-42-8) and its salts		(a) Oxidising colouring agent for hair dyeing  (b) Non-oxidising colouring agent for hair dyeing	(a) 0.5%  (b) 0.5%	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25%	
201	Phenol, 2-chloro-6-(ethylamino)-4-nitro- <sup>(15)</sup>  2-Chloro-6-ethylamino-4-nitro-phenol  CAS 131657-78-8 EINECS 411-440-1		Hair dye substance in non-oxidative hair dye products	3%	Do not use with nitrosating systems  Maximum nitrosamine content: 50 µg/kg  Keep in nitrite-free containers	Can cause allergic reaction

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
20	Phenylmethylpyrazolone (CAS No. 89-25-8) and its salts	Oxidising colouring agent for hair dyeing	0.5%	In combination with hydrogen peroxide the maximum use	
202	<p>4,4'-[1,3-Propanediylbis(oxy)]-bisbenzene-1,3-diamine and its tetrahydrochloride salt <sup>(15)</sup></p> <p>1,3-bis-(2,4-Diaminophenoxy)-propane CAS 81892-72-0 EINECS 279-845-4</p> <p>1,3-bis-(2,4-Diaminophenoxy)-propane HCl CAS 74918-21-1 EINECS 278-022-7</p>	<p>(a) Hair dye substance in oxidative hair dye products</p> <p>(b) Hair dye substance in non-oxidative hair dye products</p>	<p>(b) 1,2% as free base (1,8% as tetrahydrochloride salt)</p>	<p>(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,2% calculated as free base (1,8% as tetrahydrochloride salt).</p>	<p>(a) The mixing ratio must be printed on the label</p> <p>For (a) and (b): Can cause allergic reaction</p>

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
200	<p>1-Propanol, 3-[[4-[bis(2-hydroxy-ethyl)amino]-2-nitrophenyl]amino]<sup>(15)</sup></p> <p>HC Violet No 2 CAS 104226-19-9 EINECS 410-910-3</p>	Hair dye substance in non-oxidative hair dye products	2.00%	<p>Do not use with nitrosating systems</p> <p>Maximum nitrosamine content: 50 µg/kg</p> <p>Keep in nitrite-free</p>	Can cause allergic reaction
195	<p>Sodium 1-amino-4-(cyclohexyl-amino)-9,10-dihydro-9,10-dioxo-anthracene-2-sulphonate <sup>(15)</sup></p> <p>Acid Blue 62 CAS 4368-56-3 EINECS 224-460-9 CI 62045</p>	Hair dye substance in non-oxidative hair dye products	0.50%	<p>Do not use with nitrosating systems</p> <p>Maximum nitrosamine content: 50 µg/kg</p> <p>Keep in nitrite-free containers</p>	

Reference Number	Substance	Restrictions			Conditions of use and warnings to be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished product	Other limitations and requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
189	<p>Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenyl-azo)pyrazole-3-carboxylate and aluminum lake <sup>(15)</sup></p> <p>Acid Yellow 23 CAS 1934-21-0 EINECS 217-699-5</p> <p>Acid Yellow 23 Aluminum lake CAS 12225-21-7 EINECS 235-428-9 CI 19140</p>				
192	<p>Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate and aluminum lake <sup>(15)</sup></p> <p>Acid Red 18 CAS 2611-82-7 EINECS 220-036-2</p> <p>Acid Red 18 Aluminum lake CAS 12227-64-4 EINECS 235-438-3 CI 16255</p>	Hair dye substance in non-oxidative hair dye products	0.50%		

## ANNEX IV

### LIST OF COLOURING AGENTS ALLOWED FOR USE IN COSMETIC PRODUCTS

Field of application:

- Column 3 : Colouring agents allowed in all cosmetic products.
- Column 4 : Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes and in eye make-up and eye make-up remover.
- Column 5 : Colouring agents allowed exclusively in cosmetic products not intended to come into contact with the mucous membranes.
- Column 6 : Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
10006	Green				X	
10020	Green			X		
10316 (2)	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		

- (1) Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of these regulations shall also be allowed.
- (2) The insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted.

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
12085 (2)	Red	X				3% maximum concentration in the finished product
12120	Red				X	
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	
13015	Yellow	X				
14270	Orange	X				
14700	Red	X				
14720	Red	X				
14815	Red	X				
15510 (2)	Orange		X			
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630 (2)	Red	X				3% maximum concentration in the finished product
15800	Red			X		
15850 (2)	Red	X				
15865 (2)	Red	X				
15880	Red	X				
15980	Orange	X				
15985 (2)	Yellow	X				
16035	Red	X				
16185	Red	X				
16230	Orange			X		

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
16255 (2)	Red	X				
16290	Red	X				
17200 (2)	Red	X				
18050	Red			X		
18130	Red				X	
18690	Yellow				X	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140 (2)	Yellow	X				
20040	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
20470	Black				X	
21100	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21108	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21230	Yellow			X		
24790	Red				X	
26100	Red			X		Purity criteria: aniline ≤0.2% 2-naphtol ≤0.2% 4-aminoazobenzene ≤0.1% 1-(phenylazo)-2 naphtol ≤3% 1-[2-(phenylazo)phenylazo]-2-Naphtalenol ≤2%
27755	Black	X				
28440	Black	X				
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				
40825	Orange	X				
40850	Orange	X				
42045	Blue			X		

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
42051 (2)	Blue	X				
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	
42170	Green				X	
42510	Violet			X		
42520	Violet				X	5 ppm maximum concentration in finished product
42735	Blue			X		
44045	Blue			X		
44090	Green	X				
45100	Red				X	
45190	Violet				X	
45220	Red				X	
45350	Yellow	X				6% maximum concentration in the finished product
45370 (2)	Orange	X				Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45380 (2)	Red	X				Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45396	Orange	X				When used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1%
45405	Red		X			Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
45410 (2)	Red	X				Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
45430 (2)	Red	X				Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 3% 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid
47000	Yellow			X		
47005	Yellow	X				
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				
59040	Green			X		
60724	Violet				X	
60725	Violet	X				
60730	Violet			X		
61565	Green	X				
61570	Green	X				
61585	Blue				X	
62045	Blue				X	
69800	Blue	X				
69825	Blue	X				
71105	Orange			X		
73000	Blue	X				
73015	Blue	X				
73360	Red	X				
73385	Violet	X				
73900	Violet				X	
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				
75125	Yellow	X				
75130	Orange	X				
75135	Yellow	X				
75170	White	X				
75300	Yellow	X				
75470	Red	X				
75810	Green	X				
77000	White	X				
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				
77231	White	X				
77266	Black	X				
77267	Black	X				
77268 : 1	Black	X				
77288	Green	X				Free from chromate ions
77289	Green	X				Free from chromate ions
77346	Green	X				
77400	Brown	X				
77480	Brown	X				
77489	Orange	X				
77491	Red	X				

Colour index number or denomination	Colour	Field of application				Other limitations and requirements
Column 1	Column 2	3	4	5	6	Column 7
77492	Yellow	X				
77499	Black	X				
77510	Blue	X				Free from cyanide ions
77713	White	X				
77742	Violet	X				
77745	Red	X				
77820	White	X				
77891	White	X				
77947	White	X				
Lactoflavin	Yellow	X				
Caramel	Brown	X				
Capsanthin, capsorubin	Orange	X				
Beetroot red	Red	X				
Anthocyanins	Red	X				
Aluminium, zinc, magnesium and calcium stearates	White	X				
Bromothymol blue	Blue				X	
Bromocresol green	Green				X	
Acid red 195	Red			X		

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## **ANNEX V**

### **LIST OF SUBSTANCES EXCLUDED FROM THE SCOPE OF THESE REGULATIONS**

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Strontium and its compounds (with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed in Annex II), strontium sulphide, strontium chloride, strontium acetate, strontium hydroxide, strontium peroxide, under the conditions laid down in Annex III, and of strontium lakes, pigments and salts of the colouring agents listed with the reference (2) in Annex IV.

## ANNEX VI

### List of Preservatives which Cosmetic Products may Contain

#### Key

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

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

(\*\*\*) Solely for products which might be used for children under three years of age.

(\*\*\*\*) For other uses than preservatives, see Annex III, Part 1, No 13, 45, 54, 65, 98, 99, 100, 101, 207

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride	0,1%		
1	Benzoic acid CAS No 65-85-0  and its sodium salt CAS No 532-32-1	Rinse-off products, except oral care products: 2.5% (acid)  Oral care products: 1.7% (acid)  Leave-on products: 0.5% (acid)		
1a	Salts of benzoic acid other than that listed under reference number 1 and esters of	0.5% (acid)		

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
54	Benzalkonium chloride, bromide and saccharinate (****)  (Alkyl (C12-C22) dimethyl benzyl ammonium chloride, bromide and saccharinate	0,1% calculated as benzalkonium chloride		Avoid contact with the eyes
53	Benzethonium chloride	0.10%	(a) Rinse-off products, (b) Leave-on products other than for oral care use	
34	Benzyl alcohol (****)	1%		
55	Benzylhemiformal	0.15%	Only for products to be removed by rinsing.	
37	Bromochlorophen 6,6-Dibromo-4,4-dichloro-2,2'-methy- lene-diphenol	0,1%		
20	5-Bromo-5-nitro-1,3 dioxane	0,1%	Rinse-off products only  Avoid formation of nitrosamines.	
21	Bronopol (INN)	0,1%	Avoid formation of nitrosamines	

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride	0,3% expressed as chlorhexidine		
41	2-Chloroacetamide	0,3%		Contains chloroacetamide
11	Chlorobutanol (INN)	0,5%	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol
24	4-Chloro-m-cresol	0,2%	Prohibited in products intended to come into contact with mucous membranes	
39	Mixture of 5-Chloro-2-methylisothiazol-3 (2H)-one and 2-methylisothiazol-3 (2H)-one with magnesium chloride and magnesium nitrate	0,0015% (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol 3 (2H)-one and 2-methylisothiazol-3 (2H)-one)		
40	Chlorophene 2-Benzyl-4-chlorophenol	0,2%		
50	Chlorphenesin 3-(p-Chlorophenoxy)-propane-1,2 diol	0,3%		

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one	0,5%		
26	4-Chloro-3,5-xyleneol	0,5%		
13	Dehydroacetic acid and its salts 3-Acetyl-6-methylpyran-2,4 (3H) -dione	0,6% (acid)	Prohibited in aerosol dispensers (sprays)	
15	Dibromohexamidine and its salts (including isethionate) 3,3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine	0,1%		
22	2,4-Dichlorobenzyl alcohol	0,15%		
45	4,4-Dimethyl-1,3-oxazolidine	0,1%	The pH of the finished product not to be lower than 6	
33	DMDM Hydantoin 1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4- dione	0,6%		
49	5-Ethyl-3,7-dioxa-1-azabicyclo [3,3,0] octane	0,3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
58	Ethyl Lauroyl Arginate HCl (INCI) (*) (****)  Ethyl-N <sup>a</sup> -dodecanoyl-L-arginate hydrochloride CAS No 60372-77-2 EC No 434-630-6	0.40%	Not to be used in lip products, oral products and spray products	
14	Formic acid and its sodium salt	0,5% (expressed as acid)		
5	Formaldehyde and paraformaldehyde(****)	0,2% (except for products for oral hygiene) 0,1% (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
48	Glutaraldehyde (Pentane-1,5-dial)	0,1%	Prohibited in aerosol dispensers (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0,05%)
47	Hexamidine and its salts (including isethionate and p-hydroxybenzoate) 1,6-Di(4-amidinophenoxy)-N-hexane	0,1%		
19	Hexetidine (INN)	0,1%		

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
12	4-Hydroxybenzoic acid and its salts and esters	0,4% (acid) for 1 ester, 0,8% (acid) for mixtures of esters		
46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	0,5%		
35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)  2-pyridon and its monethanolamine salt	(a) 1%  (b) 0,5%	(a) Rinse - off products  (b) For other products	
27	Imidazolidinyl urea  3,3'-Bis (1-hydroxymethyl-2,5-dioxoimidazolidin-4-yl)-1,1'-methylenediurea	0,6%		

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
56	Iodopropynyl butylcarbamate (IPBC)  3-iodo-2-propynyl butylcarbamate CAS No: 55406-53-6	(a) rinse-off products: 0,02%  (b) leave on products: 0.01%, except in deodorants/ antiperspirants:0.0075%	Not to be used in oral hygiene and lip care products  (a) Not to be used in preparations for children under three years of age, except in bath products/ shower gels and shampoo  (b) Not to be used in body lotion and body cream (*) Not to be used in preparations for children under three years of age	(a) Not to be used for children under three years of age(**)  (b) Not to be used for children under three years of age(**)
38	4-Isopropyl-m-cresol	0.10%		
30	Methenamine (INN) Hexamethylenetetramine	0,15%		
31	Methenamine-3-chloroallylochloride (INN)	0,2%		
57	Methylisothiazolinone (INCI)	0.01%		
29	2-Phenoxyethanol	1%		
43	1-Phenoxypropan-2-ol (****)	1,0%	Rinse - off products only	

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
17	Phenylmercuric salts (including borate)	0,007% (of Hg) If mixed with other mercurial compounds authorised by these regulations, the maximum concentration of Hg to remain fixed at 0,007%	For eye make-up and eye make-up remover only	Contains phenylmercuric compounds
7	o-Phenylphenol (Biphenyl-2-ol ) and its salts	0,2% expressed as phenol		
28	Poly(1-hexamethylenebiguanide hydrochloride)	0,3%		
2	Propionic acid and its salts	2% (acid)		
3	Salicylic acid and its salts (****)	0.5% (acid)	Not to be used in preparations for children under 3 years of age, except for shampoos.	Not to be used for children under 3 years of age (Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.)

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
52	Silver chloride deposited on Titanium dioxide	0,004% calculated as AgCl	20% AgCl (w/w) on TiO <sub>2</sub>  Prohibited in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips.	
51	Sodium hydroxymethylamino acetate  Sodium hydroxymethylglycinate	0,5%		
4	Sorbic acid (Hexa-2,4-dienoic acid) and its salts	0,6% (acid)		
9	Sulphites(Inorganic) and hydrogen-sulphites (****)	0,2% expressed as free SO <sub>2</sub>		
16	Thiomersal (INN)	0,007% (of Hg) If mixed with other mercurial compounds authorised by these regulations, the maximum concentration of Hg to remain fixed at 0,007%	For eye make-up and eye make-up remover only	Contains thiomersal

Reference Number	Substance	Maximum authorised concentration in the finished product	Other limitations and requirements	Conditions of use and warnings to be printed on the label label
Column 1	Column 2	Column 3	Column 4	Column 5
23	Triclocarban (INN) (****)	0,2%	Purity criteria: 3,3',4,4'-tetra-chloroazobenzene less than 1ppm 3,3',4,4'-tetra-chloroazoxybenzene less than 1 ppm	
25	Triclosan (INN)	0,3%		
18	Undec-10-enoic acid and salts	0,2% (acid)		
8	Zinc Pyrithione (****) CAS No 13463-41-7	Hair products: 1.0% Other products: 0.5%	Rinse-off products only No use in products for oral hygiene	

## ANNEX VII

### LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised concentration in the finished product	Other limitations and requirements	
			Column 4	Column 5	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		Benzophenone-1	10%		
		Benzophenone-2 2,2',4,4'-Tetrahydroxybenzophenone	10%		
S38	4	Benzophenone-3 Oxybenzone 2-hydroxy-4-methoxybenzophenone	10%		Contains oxybenzone (Not required if concentration is 0.5% or less or when it is used only for product protection purposes)
		Benzophenone-4 Sulisobenzone 2-Hydroxy-4-methoxybenzophenone 5-sulfonic acid	5% (of acid)		
S40	22	Benzophenone-5 2-Hydroxy-4-methoxybenzophenone 5-sulphonic acid sodium salt	5% (of acid)		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised	Other limitations and	
			concentration in the finished product	requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		Benzophenone-6 2,2-Dihydroxydimethoxybenzophenone	10%		
		Benzophenone-8 2,2-Dihydroxy-4,4-dimethoxybenzophenone	3%		
		Benzophenone-9 Disodium-2,2'-dihydroxy-4,4'-dimethoxy-5,5'- disulphobenzophenone			
S61	19	3-Benzylidene Camphor	2%		
S59	9	Benzylidene camphor sulphonic acid Alpha-(2-Oxoborn-3-ylidene)toluene-4- sulphonic acid and its salts	6% (expressed as acid)		
S66	8	Butyl methoxydibenzoylmethane 1-(4-tert-butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione	5%		
S57	2	Camphor benzalkonium methosulphate N,N,N-trimethyl-4-(2-oxoborn-3-ylidene methyl)anilinium methyl sulphate	6%		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised	Other limitations and	
			concentration in the finished product	requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		Cinoxate 2-Ethoxyethyl 4-methoxycinnamate	5%		
		DEA-methoxycinnamate 4-Methoxycinnamic acid salts (potassium, sodium, diethanolamine salts)	8%		
	28	Diethylamino hydroxybenzoyl hexyl benzoate	10%		
S78	17	Diethylhexyl butamido triazone Benzoic acid, 4,4-(((1,1-dimethylethyl) amino carbonyl) phenyl amino)-1,3,5-triazine-2,4- diyl)diimino) bis-bis (2-ethylhexyl)ester)	10%		
		Digalloyl trioleate 3,4-Dihydroxy-5-(3,4,5-trihydroxy-benzoyloxy) benzoic acid trioleate	5%		
		Diisopropyl methyl cinnamate	10%		
		1-(3,4-Dimethoxyphenyl)-4,4-dimethyl-1,3 pentanedione	7%		
S74	26	Dimethycodiethyl-benzalmalonate	10%		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised	Other limitations and	
			concentration in the finished product	requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
S73	16	Drometrizole trisiloxane Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6- (2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethyl-silyl) oxy)-disiloxanyl)propyl)	15%		
		Ethyl dihydroxypropyl PABA Ethyl 4-bis(hydroxypropyl) aminobenzoate, mixed isomers	5%		
		2-Ethylhexyl dimethoxybenzylidene Dioxoimidazolidene propionate	3%		
S8	21	Ethylhexyl dimethyl PABA 4-Dimethyl-amino-benzoate of ethyl-2-hexyl	8%		
S28	12	Ethylhexyl methoxycinnamate 2-Ethylhexyl 4-methoxycinnamate	10%		
S81	25	Bis-ethylhexyloxyphenol methoxyphenyl triazine (1,3,5)-Triazine-2,4-bis(4-(2-ethyl-hexyloxy)- 2-hydroxy)-phenyl)-6-(4-methoxyphenyl)	10%		
S13	20	2-Ethylhexyl salicylate Octyl salicylate	5%		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised	Other limitations and	
			concentration in the finished product	requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
S69	15	Ethylhexyl triazone 2,4,6-Trianiilino-(p-carbo-2'-ethylhexyl-1'-oxy)- 1,3,5-triazine	5%		
		Ferulic acid	10%		
		Glyceryl ethylhexanoate dimethoxycinnamate	10%		
		Glyceryl PABA Glycerol 1-(4-aminobenzoate) 4-aminobenzoic acid-1-glyceryl ester	5%		
		4-(2-β-glucopyranosiloxy)propoxy-2-hydroxy benzophenone	5%		
		Homosalate	10%		
S27	14	Isomyl p-methoxycinnamate Isopentyl-4-methoxycinnamate (mixed isomers)	10%		
		Isopropylbenzyl salicylate	4%		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised	Other limitations and	
			concentration in the finished product	requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
		Isopropyl p-methoxycinnamate / Diisopropyl cinnamate esters mixture	10%		
		Menthyl anthranilate 5-menthyl-2-(methylethyl)cyclohexanol-2- aminobenzoate	5%		
S60	18	3-(4'-Methylbenzylidene)-d-1-camphor (4-Methylbenzylidene Camphor)	4%		
		Methylbis(trimethylsiloxy) silylisopentyl trimethoxycinnamate	7.5%		
S79	23	2,2'-Methylene-bis-6-(2H-benzotiazol-2-yl)-4- (tetramethyl-butyl)-1,1,3,3,-phenol	10%		
S80	24	Monosodium salt of 2-2'bis-(1,4-phenylene) 1H- benzimidazole-4,6-disulphonic acid	10% (of acid)		
S32	10	Octocrylene 2-Cyano-3,3-diphenyl acrylic acid, 2,3-ethylhexyl ester	10% (expressed as acid)		

Colipa Number	Reference Number	Substance	Restrictions		Conditions of use and warnings to be printed on the label
			Maximum authorised	Other limitations and	
			concentration in the finished product	requirements	
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
S3	13	PEG-25 PABA Ethoxylated ethyl-4-amino-benzoate	10%		
S45	6	Phenylbenzimidazole sulphonic acid 2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8% (expressed as acid)		
S72	11	Polyacrylamidomethyl benzylidene camphor Polymer of N-((2 and 4)-[2-oxoborn-3-ylidene methyl]benzyl) acrylamide	6%		
		TEA-salicylate Salicylic acid salts (potassium, sodium and triethanolamine salts)	2% (expressed as acid)		
S71	7	Terephthalylidene dicamphor sulphonic acid 3,3'-(1,4-phenylenedimethylidene)bis [7,7-dimethyl-2-oxobicyclo-(2,2,1-hept-1-ylmethane sulphonic acid)] and its salts	10% (expressed as acid)		
S75	27	Titanium dioxide	25%		
		Zinc oxide	Up to 25%		

## ANNEX VIII

### SYMBOLS USED ON PACKAGING/ CONTAINER

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1. Reference to enclosed or attached information



2. Period after opening



3. Date of minimum durability

