

TANZANIA FOOD AND DRUGS AUTHORITY



**GUIDELINES FOR REGISTRATION OF
COSMETIC PRODUCTS**

(Made under Section 86 of the Tanzania Food, Drugs and Cosmetics Act,
2003)

First Edition

November, 2008

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Acknowledgement

I would like to thank TFDA staff who contributed for successful development of this guideline. Acknowledgement is particularly extended to Mr. Akida Khea, Ms. Rehema Mariki, Ms. Kissa Mwamwita, Dr. N.B. Chukilizo, Mr. Iskari Fute, Mr. Legu R. Mhangwa and Mr. Felchism Apolnary.

Special thanks are also extended to TFDA esteemed stakeholders; the dealers in cosmetics, who discussed the draft guideline and gave commendable inputs for improving the guideline.

I would also like to thank the Department of Health Bureau of Food and Drugs (BFAD) of Philippines and Drug Administration and Control Authority (DACA) of Ethiopia whose documents saved as important references in drafting this guideline.

Last but not the least, TFDA Management is acknowledged for constructive comments and inputs during deliberation and approval of the guideline.

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Foreword

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, 2003 to regulate among other products, the quality and safety of cosmetics.

The regulation of cosmetics involves amongst other things, registration which is an official authorization for the purpose of marketing after assessment of quality and safety.

The guideline provides guidance to applicants to make sure that the products they manufacture or procure and apply for registration meet Tanzanian requirements.

Applicants are encouraged to familiarize with the guideline and follow it when preparing and submitting applications for registration of cosmetics. However, the requirements highlighted are minimum and whenever there will be additional information, these may be submitted to TFDA.

Adherence to this guideline will ensure that all relevant information is provided for registration of cosmetics. This will facilitate efficient and effective evaluation as well as approval process. It will also help to avoid queries which results in unnecessary delays in giving approvals.

It is anticipated that the guideline will be revised regularly in response to the experiences gathered from the utilization. We therefore welcome comments and inputs that will help in improving the guideline.

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Director General
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Introduction

This guideline is intended to assist applicants to make sure that the products they manufacture and apply for registration meet Tanzanian requirements. This is in accordance with provisions of the Tanzania Food, Drugs and Cosmetics Act, 2003 which among other things prescribes conditions of registration of cosmetics in Tanzania. Moreover, they also enable applicants to fill in the applications with the required information thereby facilitating evaluation of the cosmetic products.

This guideline applies to all products that fall within the definition of cosmetics.

The guideline is divided into the following parts:

- (a) Glossary of terms
- (b) Composition of cosmetics
- (c) Packaging and Labelling of cosmetics
- (d) Registration of cosmetics
- (e) Annex I-Application form for registration of a cosmetic

Assessment of documents submitted will be based on this guideline. Applicants are also requested to read the guideline together with the Tanzania Food, Drugs and Cosmetics Act, 2003 and Regulations made there under.

PART A: GLOSSARY OF TERMS

The terms listed below are defined specifically for the purpose of these guidelines:

“Act” means the Tanzania Food, Drugs and Cosmetics Act, 2003;

“Authority” means The Tanzania Food and Drugs Authority, or the acronym ‘TFDA’ established by Section 4 of the Act;

“Botanical” means an ingredient that is directly derived from plant and that has not been chemically modified before it is used in the preparation of a cosmetic;

“Claim” means any message or representation including pictorial, graphic, symbolic or any form of representation, which states, suggests or implies that a cosmetic has particular characteristics relating to its origin, function, nature, composition or any other characteristics;

“Composition of a cosmetic” means the ingredients contained in a cosmetic product and their proportions;

“Container” means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain a cosmetic;

“Cosmetic” means any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as component of a cosmetic, such article exclude articles intended beside the above purposes for use in the diagnosis, treatment or prevention of diseases and those intended to affect the structure or any function of the body;

“Cosmetic promotion” means and includes advertising and any other activity undertaken to increase the supply, sale, or consumption of a cosmetic;

“Decorative cosmetics” means a cosmetic intended to modify the appearance of the area to which they are applied by the use of colour;

“Fragrance” means a substance used as an ingredient of cosmetic solely to impart odour to the product;

“Ingredient of a cosmetic” means any substance which is a component of a cosmetic and includes colouring agents, botanicals, fragrance and flavour;

“International Cosmetic Ingredient Dictionary (ICID)” means the latest edition of a book that gives names of cosmetic ingredients published by the American Cosmetics Toiletries and Fragrance Association;

“International Nomenclature of Cosmetic Ingredient (INCI) name” means a name used for listing an ingredient on a cosmetic product label;

“Label of a cosmetic” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any cosmetic;

“Leaflet of a cosmetic” means and includes any written information related to a cosmetic;

“Manufacture of cosmetic” means and includes all operations involved in the production, processing, compounding, formulating, filling, refining, transforming, packing, packaging, repackaging and labelling of the cosmetics;

“Manufacturer” means a Registrant (Market Authorization Holder) engaged in the manufacture of cosmetics;

“National Standard” means a Tanzania Standard prescribed by the Tanzania Bureau of Standards (TBS);

“Package” means any box, packet or any other article in which one or more containers of cosmetics are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof;

“Preservative” means a substance which is added to a cosmetic for the primary purpose of inhibiting the development of micro-organisms in that product;

“Product” for the purpose of these guidelines, means a cosmetic;

“Product variants” means a range of cosmetics produced by the same manufacturer in the same site, similar in composition and intended for the same use but available in different colours, fragrances, flavours and container shapes;

“Prohibited Ingredient” means a substance which is forbidden to be a component of a cosmetic;

“Sell or sale” means sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for the purposes of sale, and barter or exchange supply or dispose of cosmetic, whether for a consideration or otherwise;

“Ultra Violet (UV) filter” means a substance which is added to a sunscreen cosmetic for the purpose of filtering ultra violet rays to protect the skin.

Registrant (Market Authorization Holder)

Means any person who may either be the trademark owner or person authorized by him, who has rights to sale the product and is responsible for placing the product on the Tanzanian market.

PART B: COMPOSITION OF COSMETICS.

1.0 A cosmetic intended to be placed on the Tanzanian market should not contain any of the following:

- (a) A prohibited ingredient as provided in *Annex II* of these guidelines.

- (b) Any substance listed in column b of *Annex III* of these guidelines unless the requirements in column c, d, e and f of that annex in relation to that substance are satisfied.
- (c) Any colouring agent which is not listed in *Annex IV* of these guidelines.
- (d) Any preservative listed in column 2 of *Annex V* of these guidelines unless the requirements in column 3, 4, and 5 of that Annex in relation to that preservative are satisfied.
- (e) Any preservative which is not listed in *Annex V* of these guidelines.
- (f) Any UV filter listed in column 2 of *Annex VI* of these guidelines unless the requirements in column 3 and 4 of that Annex are satisfied.

PART C: PACKAGING AND LABELLING OF COSMETICS

- 2.0 Every cosmetic shall be packaged in container made of suitable packaging materials
- 3.0 Every immediate container of any product shall be affixed with a label bearing the following particulars pertaining to the contents of such container in clearly legible and indelible letters in Kiswahili or Kiswahili and English:
 - (a) Name of a cosmetic
 - (b) Form of a cosmetic.
 - (c) Intended use of a cosmetic.
 - (d) Instructions of use of the cosmetic.
 - (e) Net content given by weight or volume, in metric system.
 - (f) Name and address of the manufacturer, including country of origin.
 - (g) Dates of manufacture and expiry of a cosmetic in clear terms
 - (h) List of ingredients in alphabetical order
 - (i) Batch or lot number.
 - (j) Precautions and warnings.
 - (k) Storage condition where applicable
- 4.0 Where the size, shape or nature of the container or package does not permit all the information provided under guideline 3.0 of these guidelines to be displayed, leaflets, pamphlets, hang tags, display panel, shrink wrap and the like shall be used. However these particulars must appear on the container;

- (a) Name of the cosmetic.
- (b) Batch or lot number.
- (c) Expiry date.

5.0 All ingredients on the label of a cosmetic shall be listed as hereunder:

- (a) List of ingredients, which will be present in the final product including both the quantity and quality specification. The name used for an ingredient shall be identified by its common name as provided for in the common ingredients nomenclature or, in the absence of nomenclature or of a common name, by its chemical name, its International Non-proprietary name as recommended by the WHO, its IUPAC or CAS Identification reference or its colour index number.
- (b) In case of decorative cosmetics marketed in a range of colour shades, all colouring agents used in the range may be listed if they are preceded by the symbol "+/-" or "±" or the phrase "may contain";
- (c) Botanicals must be listed by specifying at least genus and species portions.
- (d) Ingredients must be listed in descending order of predominance, in their concentration by weight;
- (e) Ingredients that are present at a concentration of 1% or less and all colouring agents, regardless of their concentration may be listed in random order after the ingredients that are present at a concentration of more than 1%.

PART D: REGISTRATION OF COSMETICS.

6.0 An application for registration of a cosmetic will be made by a registrant. Such registrant shall be a person who is resident in Tanzania or a company incorporated in Tanzania. All application documents must be in English or Kiswahili.

7.0 Every registrant who intends to sell any cosmetic in Tanzania shall;

- (a) Apply for registration of the cosmetic to the Authority by submitting a duly filled in application form as provided in Annex I of these guidelines accompanied with two samples of the product. The submission shall be both in hard copy and in electronic form on a CD-Rom in a PDF format, bookman old style point 12.
- (b) Submit separate application for each product or product variant.
- (c) Pay Evaluation and registration fee of US\$75.00 for imported or US\$ 45.00 for locally manufactured cosmetic. Applications for registration of product variant shall be charged half of the prescribed fee.

- 8.0 An application shall only be accepted and processed if all of the conditions hereunder are complied with:
- (a) Submission of duly filled in application form
 - (b) Payment of evaluation and registration fee
 - (c) Application filed in a spring A4 size file with collapsible edge made of biodegradable material. Arch lever file is strictly not permissible.
- 9.0 The authority shall grant registration of a cosmetic if it is satisfied that:
- (a) The cosmetic intended to be registered complies with the National Standards or where there are no National Standards, complies International Standards;
 - (b) The cosmetic complies with requirements prescribed in these guidelines and;
 - (c) The cosmetic complies with the criteria for "total viable count" and absence of "specific organisms" as prescribed in the *Annex VII* of these guidelines.
- 10.0 The Authority may during assessment of application require the registrant to submit samples, documents, and information and give clarification as the case may be. The processing of an application shall be kept on hold until such samples, documents, information or clarification is provided.
- 11.0 If the registrant fails to respond to the issues in section 10.0 within 90 days from the date of request the application shall expire and the registration of the product may only be considered upon submission of a new application as prescribed in section 7.0 of these guidelines.
- 12.0 The Authority after being satisfied that the cosmetic complies with requirements prescribed in these guidelines; it will inform the registrant in writing that the cosmetic has been granted market authorization.
- 13.0 Where the Authority refuses to approve the registration of a cosmetic; it shall notify the registrant in writing of such decision and the reason(s) thereof.
- 13.1 If the registrant is not satisfied with the decision of the Authority he may, within 30 days from the date of notification furnish the Director General with representations for the Authority to review its decision;
- 13.2 The Authority after considering the submitted representations may grant registration to the cosmetic or if not satisfied it will not grant registration.
- 13.3 Any registrant who is aggrieved by a decision of the Authority in relation to any application may within 60 days from the date on which the Authority made the decision that is the subject of complaint, lodge and appeal in writing to the Minister
- 14.0 The registration of cosmetic shall be valid for three years unless suspended, cancelled or revoked by the Authority or withdrawn by a registrant.

- 15.0 If for any reason the registrant changes any matter related to a registered cosmetic including but not limited to change of composition, packaging, labelling or any other change, shall, before selling the changed cosmetic, notify and obtain approval of the Authority of the change. The notice to the Authority shall be accompanied with the reason(s) for such change.
- 15.1 The Authority will evaluate reasons provided in the notice referred to under 15.0 and if satisfied with such reasons it will approve the changes by issuing approval notice and if it is not satisfied it will not approve the changes and it will notify the registrant the reasons thereof.
- 16.0 The registrant may at any time by giving notice in writing to the Authority withdraw the registration of the registered cosmetic.
- 17.0 Every registrant shall be responsible for:
- (a) All information supplied in support of the application for registration and variation thereof;
 - (b) Ensuring safety and quality of the registered cosmetic and that the product complies with all requirements as provided in these guidelines;
 - (c) Effect voluntary and compulsory product recall whenever necessary.
 - (d) Observation of sanitation and hygiene in manufacturing premises and equipment.

ANNEX I

TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FORM FOR REGISTRATION OF A COSMETIC

(For official use only)

Application No:

ATTACHMENTS

Please attach/enclose:-

- (a) CD containing a dully fill in application form in soft form in text format on excel
- (b) A copy of certificate of incorporation for companies or registration of the other forms of ownership of the Business in Tanzania.
- (c) A copy of free sale certificate and or certificate of observance to Good Manufacturing Practice for imported cosmetics.
- (d) Art work of immediate package, outer package and product information leaflet
- (e) Authorization letter permitting an importer to apply on behalf of his principal.

1.0 Product Particulars

1.1 Name of cosmetic:

1.2 Form of cosmetic: (see explanatory notes)

1.3 Physical description of a cosmetic

1.4 Intended use: (see explanatory notes)

1.5 Method of use:

1.6 Pack size(s):

1.7 Formula of a cosmetic:

S/N	INCI name	Chemical name	% proportion	Reason for inclusion

Note

If the formula is considered to be confidential seal in an envelope and mark confidential and then attach.

1.8 Brief description of the type and properties of packaging material and the seal and its liner if any and provide justification for the suitability of the packaging material and the seal and its liner used.

1.9 Brief description of the method used for the determination of shelf life.

1.10 Recommended storage conditions (where applicable) including any relevant information after the product is opened for use or reconstituted:

1.11 Recommended shelf-life:

2.0 Particulars of Registrant

(a) Name: _____

Physical Address: _____

Postal Address: _____

Country: _____

Phone: _____ Fax: _____ Email: _____

(b) Status of applicant (tick where appropriate)

Manufacturer _____ Importer _____

3.0 Particulars of manufacturer

Name: _____

Physical address: _____

Postal address: _____

Country: _____

4.0 Particulars of local agent or importer

Name: _____

Physical address: _____

Postal address: _____

Country: _____

Phone: _____ Fax: _____ E-mail: _____

Phone: _____ Fax: _____ E-mail: _____

5.0 Declaration by the registrant

I, the undersigned certify that all the information in this form and accompanying documentation is correct and true to the best of my knowledge. I also declare that the product does not contain substances from the prohibited list and/ or substances that exceeds the level permitted.

Name: _____

Position: _____

Signature: _____

Official stamp:

Date: _____

6.0 Fees/charges payment (For official use only)

Fee to be paid.....

Name and signature of Authorized officer.....

Name and signature of cashier.....

Receipt number.....

Date and stamp.....

NB: Cashier should attach copy of receipt

EXPLANATORY NOTES

1. FORMS OF COSMETICS

Aerosol - All types, already pressurized e.g., some hair sprays, perfumes

Capsule/Tablet - e.g., bath oil capsules

Clear Non-oily Liquid - e.g., solutions, some lotions

Clear Oil - e.g., mineral oil

Cream - Viscous liquid or semi-solid emulsion (e.g., some hair grooming products, makeup).

Gel - Viscous, usually clear, jelly-like semi-solids (e.g., some hair grooming products, dentifrices).

Granules - e.g., bath pellets, crystals, pearls, etc

Kit - If the product consists of two or more components of different forms which are mixed before use, then insert "Kit" and write in brackets the forms of the various components.

Liquid Suspension - Solid in liquid (e.g., some moisturizers).

Lotion - Liquid emulsion e.g., some moisturizers, makeup.

Ointment - A semisolid preparation based on a fatty material (e.g., lanolin)

Paste - Concentrate of absorptive powders usually dispersed in semi-solid base (e.g., dentifrice.)

Pencil - e.g., eyebrow pencil

Powder – Loose: e.g., dusting powder, makeup, talcum

Powder – Pressed: e.g., blush, eye makeup

Pressed Cake - e.g., soap, bath bar

Pump Spray - e.g., atomizers, some hair sprays

Stick - e.g., lipsticks, some deodorants

Other (Please Specify) - Product which does not fall into one of the general categories above. Please provide the rationale as to why the form is unique.

2. INTENDED USE

Antiwrinkle Preparation:

Product applied as a makeup or moisturizer generally to the face to mask or reduce the appearance of fine lines or wrinkles. (See also, Eye Lotion and Eye Makeup).

Baby Product:

Product labeled for use on infants 2 years old or less.

Barrier Cream:

Product which protects the hands from dirt, grease, solvents, etc.

Bath Preparation:

Product added to the bath water. Includes bath oils, tablets, salts, bubble baths, etc.

Body Makeup:

Product applied as makeup to the body excluding the hair, eyes or face. Includes leg and body paints. (See also, Eye Makeup and Face makeup.)

Dentifrice:

Product which cleans and/or polishes the teeth.

Deodorant:

Product which modifies, reduces, or prevents the development of body odors. Excludes genital deodorants and products which claim to reduce perspiration.

Douche:

Product used for personal feminine hygiene. (See also, Genital Deodorant.)

Eye Lotion:

Non-makeup product specifically indicated for use in the area of the eye. Includes lotions and moisturizers.

Eye Makeup:

Product specifically indicated for use in the area of the eye. Includes eyebrow pencils, eyeliners, eye shadows, eye makeup removers, mascara, etc.

Face Makeup:

Product for use in the area of the face. Includes blushes, face powders, foundations, rouges, makeup fixatives, etc. (See also, Antiwrinkle Preparation, Eye Lotion, Eye Makeup, Lipstick and Skin Moisturizer.)

Fragrance:

Includes perfumes, colognes, toilet water, dusting and talcum powders.

Genital Deodorant:

Deodorant/Cleanser intended for use in the genital area. (Includes non-douche feminine hygiene products.)

Genital Lubricant:

Product for use as a lubricant in the genital area.

Hair Bleach:

Product which bleaches the hair. Excludes hair lighteners with colours.

Hair Conditioner:

Non-shampoo product which increases the suppleness or body of the hair, facilitates combing, adds gloss or texture to the hair, etc. (See also, Hair Shampoo.)

Hair Dye:

Product which changes the colour of the hair

Hair Grooming:

Product which improves the appearance or is used to shape/style the hair. Includes mousses, gels, pomades, sprays etc. (See also, Hair Straightener and Hair Waving Preparation.)

Hair Removal:

Depilatory/epilatory product which facilitates the removal of hair by chemical or mechanical means. Includes wax treatments. (See also, Shaving Preparation.)

Hair Shampoo:

Product which cleanses and conditions the hair. Product is washed off after use.

Hair Straightener:

Product which contain agents which chemically soften the hair to facilitate straightening of the hair.

Nail lacquer (Nail polish)

Products which changes the colour of the nail.

Nail polish remover

Products which removes the colour from the nail.

ANNEX II

Regulation 6(1) (a)

LIST OF PROHIBITED INGREDIENTS

S/N	Substance
1.	(1R,2S)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)
2.	(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethanonaphthalene (isodrin-ISO)
3.	(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethanonaphthalene (endrin-ISO)
4.	(2-isopropylpent-4-enoyl)urea (apronalide)
5.	β -Acetoxyethyl trimethylammonium hydroxide (acetylcholine and its salts)
6.	(Oxalylbisiminoethylene) bis [(O-chlorobenzyl) diethylammonium] salts, <i>e.g.</i> ambenonium chloride
7.	α -Piperidin-2-yl benzyl acetate laevorotatory threoform (Levophacoperane) and its salts
8.	α -Santonin ((3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphtho (1,2-b) furan-2,8-dione
9.	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diodophenyl] acetic acid and its salts
10.	1,1-Bis (dimethylaminomethyl) propyl benzoate (amydracaine, alypine) and its salts
11.	1,1,3,3,5-Pentamethyl-4,6-dinitroindane (moskene)
12.	1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO) (lindane)
13.	1,2-Epoxybutane
14.	1,3-dimethylpentylamine and its salts
15.	11 α -Hydroxypregn-4-ene-3, 20-dione and its esters
16.	1-and 2-Naphthylamines and their salts
17.	1-Butyl-3-(N-crotonoylsulphanilyl) urea
18.	1-Dimethylaminomethyl-1 -methylpropyl benzoate (amylocaine) and its salts
19.	1-Methoxy-2,4-diaminobenzene (2,4 - diaminoanisole - Cl 76050) and their salts
20.	1-Methoxy-2,5-diaminobenzene (2,5 - diaminoanisole) and their salts
21.	2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts
22.	2-(4-Methoxybenzyl-N-(2-pyridyl)amino)ethyl dimethylamine maleate
23.	2- α -Cyclohexylbenzyl (N,N,N',N'-tetraethyl) trimethylenediamine (phenetamine)
24.	2,2,2-Tribromoethanol (tribromoethyl alcohol)
25.	2,2,2-Trichloroethane-1,1-diol

S/N	Substance
26.	2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts
27.	2,2'-Dihydroxy-3,3',5,5',6,6'--hexachlorodiphenylmethane (Hexachlorophene)
28.	2,3,7,8,-Tetra chlorodibenzo-p-dioxin
29.	2,3-Dichloro-2-methylbutane
30.	2,4-Diaminophenylethanol and its salts
31.	2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)
32.	2-[2-(4-Chlorophenyl)-2-phenylacetyl] indan 1,3-dione (chlorophacinone-ISO)
33.	2-Amino-1,2-bis (4-methoxyphenyl) ethanol and its salts
34.	2-Amino-4-nitrophenol
35.	2-Amino-5-nitrophenol
36.	2-Chloro-6-methylpyrimidin-4-yldimethylamine (crimidine-ISO)
37.	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts
38.	2-Methylheptylamine and its salts
39.	2-Methyl-m-phenylenediamine
40.	2-Naphthol
41.	2-Phenylindan-1,3-dione (phenindione)
42.	3-(1-Naphthyl)-4-hydroxycoumarin
43.	3,3- Bis(4-hydroxyphenyl)phthalide (Phenolphthalein)
44.	3,4',5-Tribromosalicylanilide
45.	3,4,5-Trimethoxyphenethylamine and its salts
46.	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H,pyrano(3,2-c)-(1) benzopyran-5-one (cyclocoumarol)
47.	3-Diethylaminopropyl cinnamate
48.	3'-ethyl-5',6',7,8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonaphthone or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronaphthalen
49.	3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)
50.	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin
51.	4-Amino-2-nitrophenol
52.	4-Aminosalicylic acid and its salts
53.	4-Benzyloxyphenol, 4- methoxyphenol and 4-ethoxyphenol
54.	4-Ethoxy-m-phenylenediamine and its salts
55.	4-Methyl-m-phenylenediamine and its salts
56.	4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
57.	4-Phenylbut-3-en-2-one
58.	4-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette)

S/N	Substance
59.	4-tert-Butylphenol
60.	4-tert-Butylpyrocatechol
61.	5-(α , β -Dibromophenethyl)-5-methylhydantoin
62.	5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypiodite
63.	5,5-Diphenyl-4-imidazolidone
64.	5-tert-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene)
65.	6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (minoxidil) and its salts
66.	7-[2-Hydroxy-3-(2-hydroxyethyl)-N-methylamino]propyl] theophylline (xanthinol)
67.	Acenocoumarol
68.	Acetonitrile
69.	Aconitine (principal alkaloid of <i>Aconitum napellus</i> L.) and its salts
70.	<i>Aconitum napellus</i> L. (leaves, roots and galenical preparations)
71.	<i>Adonis vernalis</i> L. and its preparations
72.	Alkali pentacyanonitrosylferrate (2-)
73.	Alkyne alcohols, their esters, ethers and salts
74.	Alloclamide and its salts
75.	Allyl isothiocyanate
76.	Aminocaproic acid and its salts
77.	Amitriptyline and its salts
78.	<i>Ammi majus</i> and its galenical preparations
79.	Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))
80.	Amyl nitrites
81.	<i>Anamirta cocculus</i> L. (fruit)
82.	Aniline, its salts and its halogenated and sulphonated derivatives
83.	Anthracene oil
84.	Anti-androgens of steroidal structure
85.	Antibiotics
86.	Antimony and its compounds
87.	<i>Apocynum cannabinum</i> L. and its preparations
88.	Apomorphine (5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo (de,g)-quinoline-10, 11 - dihydric alcohol) and its salts
89.	Arecoline
90.	Aristolochic acid and its salts; <i>Aristolochia</i> spp. and their preparations
91.	Arsenic and its compounds
92.	<i>Atropa belladonna</i> L. and its preparations
93.	Atropine, its salts and derivatives

S/N	Substance
94.	Azacyclonol and its salts
95.	Barbiturates
96.	Barium salts with the exception of barium sulphate, barium sulphide under the conditions laid down in second schedule and lakes, salts and pigments prepared from the colouring agents listed in table 3 of the third schedule
97.	Bemegride and its salts
98.	Benactyzine
99.	Bendroflumethiazide and its derivatives
100.	Benzatropine and its salts
101.	Benzazepines and benzadiazepines
102.	Benzene
103.	Benzidine
104.	Benzilium bromide
105.	Benzimidazol-2(3H)-one
106.	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used
107.	Benzoyl peroxide
108.	Beryllium and its compounds
109.	Betoxycaine and its salts
110.	Bietamiverine
111.	Bithionol
112.	Bretylium tosilate
113.	Bromine, elemental
114.	Bromisoval
115.	Brompheniramine and its salts
116.	Brucine
117.	Butanilcaine and its salts
118.	Butopiprine and its salts
119.	Cadmium and its compounds
120.	<i>Calviceps purpurea Tul.</i> , its alkaloids and galenical preparations
121.	Cantharides, <i>Cantharis vesicatoria</i>
122.	Captodiame
123.	Caramiphen and its salts
124.	Carbon disulphide
125.	Carbon Tetrachloride
126.	Carbromal
127.	Carbutamide

S/N	Substance
128.	Carisoprodol
129.	Catalase
130.	Catechol
131.	Cells, tissues or products of human origin
132.	Cephaeline and its salts
133.	<i>Chenopodium ambrosioides</i> (essential oil)
134.	Chlorine
135.	Chlorofluorocarbons (CFCs)
136.	Chlormethine and its salts
137.	Chlormezanone
138.	Chloroethane
139.	Chloroform
140.	Chlorphenoxamine
141.	Chlorpropamide
142.	Chlorprothixene and its salts
143.	Chlortalidone
144.	Chlorzoxazone
145.	Choline salts and their esters, <i>e.g.</i> choline chloride
146.	Chromium; chromic acid and its salts
147.	Cinchocaine and its salts
148.	Cinchophen, its salts, derivatives and salts of these derivatives
149.	Clofenamide
150.	Clofenotane; DDT (ISO)
151.	Cobalt benzenesulphonate
152.	Colchicine , its salts and derivatives
153.	Colchicoside and its derivatives
154.	<i>Colchicum autumnale L.</i> and its galenical preparations
155.	Colouring agent C.I. 42 640
156.	Colouring agent CI 12075 and its lakes, pigments and salts
157.	Colouring agent CI 12140
158.	Colouring agent CI 13065
159.	Colouring agent CI 15585
160.	Colouring agent CI 26105
161.	Colouring agent CI 42535
162.	Colouring agent CI 42555 Colouring agent CI 42555-1 Colouring agent CI 42555-2

S/N	Substance
163.	Colouring agent CI 45170 and CI 45170:1
164.	Colouring agent CI 61554
165.	Coniine
166.	<i>Conium maculatum L.</i> (fruit, powder, galenical preparations)
167.	Convallatoxin
168.	Coumetarol
169.	Croton tiglium (oil)
170.	Crude and refined coal tars
171.	Curare and curarine
172.	Cyclarbamate
173.	Cyclizine and its salts
174.	Cyclomenol and its salts
175.	Cyclophosphamide and its salts
176.	<i>Datura stramonium L.</i> and its galenical preparations
177.	Deanol aceglumate
178.	Decamethylenebis (trimethylammonium) salts, <i>e.g.</i> decamethonium bromide
179.	Dextromethorphan and its salts
180.	Dextropropoxyphene
181.	Dibromosalicylanilides
182.	Dichloroethanes (ethylene chlorides)
183.	Dichloroethylenes (acetylene chlorides)
184.	Dichlorosalicylanilides
185.	Dicoumarol
186.	Diethyl 4-nitrophenyl phosphate
187.	Difenclozazine
188.	Digitaline and all heterosides of <i>Digitalis purpurea L.</i>
189.	Dihydrotachysterol
190.	Dimethyl sulfoxide
191.	Dimethylamine
192.	Dimethylformamide
193.	Dimevamide and its salts
194.	Dinitrophenol isomers
195.	Dioxane
196.	Dioxethedrin and its salts
197.	Diphenhydramine and its salts
198.	Diphenoxylate hydrochloride

S/N	Substance
199.	Diphenylpyraline and its salts
200.	Disulfiram; thiram (ISO)
201.	Dithio-2,2'-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) - (pyrithione disulphide + magnesium sulphate)
202.	Doxylamine and its salts
203.	Emetine, its salts and derivatives
204.	Ephedrine and its salts
205.	Epinephrine
206.	Ergocaciferol and cholecalciferol (vitamins D2 and D3)
207.	Eserine or physostigmine and its salts
208.	Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in fifth schedule
209.	Ethionamide
210.	Ethoheptazine and its salts
211.	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid
212.	Ethylene oxide
213.	Ethylphenacemide
214.	Fenadiazole
215.	Fenozolone
216.	Fenylramidol
217.	Fluanisone
218.	Fluoresone
219.	Fluorouracil
220.	Furazolidone
221.	Furfuryltrimethylammonium salts, <i>e.g.</i> furtrethonium iodide*
222.	Furocoumarines (<i>e.g.</i> trioxysalan, 8-methoxypsoralen, 5-methoxypsoralen), except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarins shall be below 1 mg/kg.
223.	Galantamine
224.	Gallamine triethiodide
225.	Glucocorticoids
226.	Glutethimide and its salts
227.	Glycyclamide
228.	Gold salts
229.	Guaifenesin
230.	Guanethidine and its salts
231.	Haloperidol
232.	Hexachloroethane

S/N	Substance
233.	Hexaethyl tetraphosphate
234.	Hexamethylenebis (trimethylammonium) salts, <i>e.g.</i> hexamethonium bromide*
235.	Hexapropymate
236.	Hydrastine, hydrastanine and their salts
237.	Hydrazides and their salts
238.	Hydrazine, its derivatives and their salts
239.	Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in second schedule
240.	Hydroquinone except under conditions of use stated in second schedule
241.	Hydrogen cyanide and its salts
242.	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in No.51 in second schedule
243.	Hydroxyzine
244.	Hyoscine, its salts and derivatives
245.	Hyoscyamine, its salts and derivative
246.	<i>Hyoscyamus niger L.</i> (leaves, seeds, powder and galenical preparations)
247.	Inorganic nitrites, with the exception of sodium nitrite
248.	Inproquone
249.	Iodine
250.	Ipecacuanha (<i>Cephaelis ipecacuanha Brot.</i> And related species) (roots, powder and galenical preparations)
251.	Isocarboxazide
252.	Isometheptene and its salts
253.	Isoprenaline
254.	Isosorbide dinitrate
255.	<i>Juniperus sabina L.</i> (leaves, essential oil and galenical preparations)
256.	Lead and its compounds, with the exception of that mentioned in second schedule No.55 under the conditions stated
257.	Lidocaine
258.	Imperatorin [9-(3-methylbut-2-enyloxy) furo(3,2-g) chromen-7-one]
259.	<i>Lobelia inflata L.</i> and its galenical preparations
260.	Lobeline and its salts
261.	Lysergide and its salts
262.	Malononitrile
263.	Mannomustine and its salts
264.	Mecamylamine
265.	Mefeclozazine and its salts

S/N	Substance
266.	Mephenesin and its esters
267.	Meprobamate
268.	Mercury and its compounds except those special cases included in fourth schedule.
269.	Metaldehyde
270.	Metamfepramone and its salts
271.	Metethoheptazine and its salts
272.	Metformin and its salts
273.	Methapyrilene and its salts
274.	Metheptazine and its salts
275.	Methocarbamol
276.	Methotrexate
277.	Methylphenidate and its salts
278.	Methyprylon and its salts
279.	Metyrapone
280.	Mofebutazone
281.	Morpholine and its salts
282.	N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium salts, <i>e.g.</i> isopropamide iodide
283.	N-(Trichloromethylthio)-4- cyclohexene-1,2-dicarboximide (Captan)
284.	N, N-bis (2-chloroethyl) methylamine N-oxide and its salts
285.	N,N'-[(Methylimino)diethylene]bis(ethyltrimethylammonium) salts, <i>e.g.</i> azamethonium bromide
286.	N,N'-Pentamethylenebis (trimethylammonium) salts, <i>e.g.</i> Pentamethonium bromide
287.	N-5-Chlorobenzoxazol-2-ylacetamide
288.	Nalorphine, its salts and ethers
289.	Naphazoline and its salts
290.	Narcotics, natural and synthetic: All substances listed in Table I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961.
291.	Neodymium and its salts
292.	Neostigmine and its salts (<i>e.g.</i> neostigmine bromide)
293.	Nicotine and its salts
294.	Nitrobenzene
295.	Nitrocresols and their alkali metal salts
296.	Nitroderivatives of carbozol
297.	Nitrofurantoin

S/N	Substance
298.	Nitrosamines
299.	Nitrostilbenes, their homologues and their derivatives,
300.	Nitroxoline and its salts
301.	Noradrenaline and its salts
302.	Noscapine and its salts
303.	O,O-Diacetyl-N-allyl-N-normorphine
304.	O,O-Diethyl O-4-nitrophenyl phosphorothioate (parathion-ISO)
305.	Octamoxin and its salts
306.	Octamylamine and its salts
307.	Octodrine and its salts
308.	Oestrogens
309.	Oil from the seeds of <i>Laurus nobilis L.</i>
310.	Oleandrin
311.	o-Phenylenediamine and its salts
312.	Oxamide and its derivatives
313.	Oxpheneridine and its salts
314.	Paramethasone
315.	Parethoxycaine and its salts
316.	Pelletierine and its salts
317.	Pemoline and its salts
318.	Pentachloroethane
319.	Pentaerithrityl tetranitrate
320.	Petrichloral
321.	Phenacemide
322.	Phenaglycodol
323.	Phenmetrazine, its derivatives and salts
324.	Phenothiazine and its compounds
325.	Phenprobamate
326.	Phenprocoumon
327.	Phenylbutazone
328.	Phosphorus and metal phosphides
329.	<i>Physostigma venenosum Balf.</i>
330.	<i>Phytolacca Spp.</i> and their preparations
331.	Picric acid
332.	Picrotoxin
333.	Pilocarpine and its salts

S/N	Substance
334.	<i>Pilocarpus jaborandi</i> Holmes and its galenical preparations
335.	Pipazetate and its salts
336.	Pipradrol and its salts
337.	Piprocurarium
338.	Poldine methylsulfate
339.	Pramocaine
340.	Probenecid
341.	Procainamide, its salts and derivatives
342.	Progestogens
343.	Propane-1 2,3-triyl trinitrate
344.	Propatylnitrate
345.	Propyphenazone
346.	<i>Prunus laurocerasus</i> L. ('cherry laurel water')
347.	Psilocybine
348.	<i>Pyrethrum album</i> L. and its galenical perparations
349.	Pyrithione sodium (INNМ)
350.	Pyrogallol
351.	Radioactive substances (1)
352.	<i>Rauwolfia serpentina</i> alkaloids and their salts
353.	Safrole except for normal content in the natural essences used and provided the concentration does not exceed: <ul style="list-style-type: none"> ▪ 100 ppm in the finished product ▪ 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children.
354.	Salts of O-alkyldithiocarbonic acids
355.	<i>Schoenocaulon officinale</i> Lind. (seeds and galenical perparations)
356.	Secondary dialkanolamines
357.	Selenium and its compounds with the exception of selenium disulphide under the conditions set out under the reference No. 49 in second schedule
358.	Sodium hexacyclonate
359.	<i>Solanum nigrum</i> L. and its galenical preparations
360.	Sparteine and its salts
361.	Spirolactone
362.	Steroids in any proportions
363.	Strontium lactate
364.	Strontium nitrate
365.	Strontium polycarboxylate

S/N	Substance
366.	Strophantines, their aglucones and their respective derivatives
367.	<i>Strophantus</i> species and their galenical preparations
368.	Strychnine and its salts
369.	<i>Strychnos</i> species and their galenical preparations
370.	Substances with androgenic effect
371.	Succinonitrile
372.	Sulfinpyrazone
373.	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH ₂ groups) and their salts
374.	Sultiame
375.	Sympathomimetic amines acting on the central nervous system: any substance contained in the list of medicaments which are subject to medical prescription.
376.	Synthetic curarizants
377.	Tefazoline and its salts
378.	Tellurium and its compounds
379.	Tetrabenazine and its salts
380.	Tetrabromosalicylanilides
381.	Tetracaine and its salts
382.	Tetrachloroethylene
383.	Tetrachlorosalicylanilides
384.	Tetraethyl pyrophosphate; TEPP (ISO)
385.	Tetrahydrozoline and its salts
386.	Tetrylammonium bromide
387.	Thalidomide and its salts
388.	Thallium and its compounds
389.	<p>(a) The skull, including the brain and eyes, tonsil and spinal cord of:</p> <ul style="list-style-type: none"> - bovine animals aged 12 month - ovine and caprine animals which are aged over 12 months or have a permanent incissor tooth erupted through the gum; <p>(b) the spleens of ovine and caprine animals and ingredients derived there from. However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:</p> <ul style="list-style-type: none"> - transesterification or hydrolysis at least 200 °C and at appropriate corresponding pressure, for 20 minutes (glycerol and fatty acids and esters); - saponification with NaOH 12M (glycerol and soap): - batch process: at 95°C for 3 hours or continuous process: at 140°C, 2 bars (2000 hPa) for 8 minutes or equivalent conditions.
390.	<i>Thevetia nerifolia</i> Juss. glycoside extract

S/N	Substance
391.	Thiamazole
392.	Thiotepa
393.	Thiourea and its derivatives, with the exception of the one listed in second schedule
394.	Thiuram disulphides
395.	Thiuram monosulphides
396.	Thyropropic acid and its salts
397.	Thyrothricine
398.	Tolboxane
399.	Tolbutamide
400.	Toluidines, their isomers, salts and halogenated and sulphonated derivatives
401.	Tranlycypromine and its salts
402.	Tretamine
403.	Tretinoin (retinoic acid and its salts)
404.	Triamterence and its salts
405.	Trichlormethine and its salts
406.	Trichloroacetic acid
407.	Trichloronitromethane (chloropicrine)
408.	Trifluperidol
409.	Triparanol
410.	Tripelennamine
411.	Tritolyl phosphate
412.	Tuaminoheptane, its isomers and salts
413.	<i>Urginea scilla Stern.</i> and its galenical preparations
414.	Vaccines, toxins or serums listed in the Annex to the second European Union 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 N L 147, 9.6.1975, p. 13)
415.	Valnoctamide
416.	Veratrine, its salts and galenical preparations
417.	<i>Veratrum Spp.</i> And their preparations
418.	Vinyl chloride monomer
419.	Warfarin and its salts
420.	Xylidines, their isomers, salts and halogenated and sulphonated derivatives
421.	Xylometazoline and its salts
422.	Yohimbine and its salts
423.	Zirconium and its compounds, with the exception of the substances listed

S/N	Substance
	under No.50 in second schedule.
424.	Zoxazolamine

ANNEX III

Regulation 6 (1) (b)

LIST OF SUBSTANCES NOT ALLOWED IN COSMETICS EXCEPT UNDER SPECIAL CONDITIONS

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1a	Boric acid, borates and tetraborates	<p>(a) Talc</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) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)</p> <p>(b) 1. Not to be used in products for children under 3 years of age</p> <p>(c) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)</p>	<p>(a) 1. Not to be used for children under 3 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 for children under 3 years of age</p> <p>(c) 1. Not to be used for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin</p>

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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 3 years of age	(a) Not to be used of bathing children under 3 years of age (b) Rinse well
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 7-9.5 - 11% ready for use pH 7-9.5 - 5% ready for use pH 7-12.7 - 2% ready for use pH 7-9.5 Percentages calculated as thioglycolic acid.	a) b) c) The directions for use 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 instruction. - Keep out of reach of children.

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
2b	Thioglycolic acid esters	<p>Hair waving or straightening products:</p> <ul style="list-style-type: none"> - General use - Professional use 	<ul style="list-style-type: none"> - 8% ready for use pH 6-9.5 - 11% ready for use pH 6-9.5 <p>Percentages calculated as thioglycolic acid.</p>	<p>The directions for use must obligatorily incorporate the following sentences:</p> <ul style="list-style-type: none"> ▪ May cause sensitisation in the event of skin contact. ▪ Avoid contact with eyes. ▪ In the event of contact with eyes, rinse off with plenty of water and seek medical advice. ▪ Wear suitable gloves. 	<ul style="list-style-type: none"> - Contains thioglycollate. - Follow the instructions. - Keep out of reach of children. - For professional use only.
3	Oxalic acid, its esters and alkaline salts	Hair care products	5%		- For professional use only
4	Ammonia		6% calculated as NH ₃		- Above 2%: contains ammonia
5	Tosylchloramide sodium (*)		0.2%		
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5% (b) 3%		
7	Dichloromethane		35% (when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35%)	0.2% as maximum impurity content	

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
8	m- and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted derivatives of o-phenylenediamines (1)	Oxidizing colouring agents for hair dyeing (a) General use (b) Professional use	6% calculated as free base		(a) - Can cause an allergic reaction - Contains phenylenediamines - Do not use to dye eyelashes or eyebrows (b) - For professional use only. - Contains phenylenediamines - Can cause an allergic reaction. - Wear suitable gloves
9	Methylphenylenediamines, their N-substituted derivatives and their salts (1) with the exception of substance N°364 and 413 in first schedule	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10% calculated as free base		(a) - Can cause an allergic reaction - Contains phenylenediamines - Do not use to dye eyelashes or eyebrows. (b) - For professional use only. - Contains phenylenediamines - Can cause an allergic reaction. - Wear suitable gloves.
10	Diaminophenols (1)	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10% calculated as free base		(a) - Can cause an allergic reaction. - Contains diaminophenols. - Do not use to dye eyelashes or eyebrows. (b) For professional use only. - Contains diaminophenols. - Can cause an allergic reaction. - Wear suitable gloves.

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
11	Dichlorophen (*)		0.5%		- Contains dichlorophen
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	12% H ₂ O ₂ (40 volumes) present or released 4% of H ₂ O ₂ present of released 2% of H ₂ O ₂ present or released 0.1% of H ₂ O ₂ present or released		(a) (b) (c) - Contains hydrogen peroxide. - Avoid contact with eyes. - Rinse eyes immediately if product comes into contact with them. (a) Wear suitable gloves.
13	Formaldehyde	Nail hardeners	5% calculated as formaldehyde		Protect cuticles with grease or oil. Contains formaldehyde (2)

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
14	Hydroquinone (1)	Oxidizing colouring agent for hair-dyeing 1. General use 2 Professional use	0.3%		(a) 1. - Do not use to dye eyelashes or eye brows - Rinse the eyes immediately if the product comes into contact with them - Contains hydroquinone 2. - For professional use only - Contains hydroquinone - Rinse the eyes immediately if the product comes into contact with them (b) - Contains hydroquinone - Avoid contact with the eyes - Apply to small areas - If irritation develops discontinue use areas - Do not use on children under the age of 12

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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 (3) (b) 1. 2% by weight (3) 2. 4.5% by weight (3) (c) up to pH 12.7 (d) up to pH 11		(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. - For professional use only - Avoid contact with eyes - Can cause blindness (c) - Keep out of reach of children. - Avoid contact with eyes
15b	Lithium hydroxide	(a) Hair straightener 1. General use 2. Professional use (b) Other uses	(a) 1. 2% by weight (1) 2. 4.5% by weight (1)		(a) 1. -Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children 2. - For professional use only - Avoid contact with eyes - Can cause blindness
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) Other uses	(a) 7% by weight calcium hydroxide		(a) - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children

Reference number	Substance	RESTRICTIONS			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
16	Alpha-naphthol	Colouring agent for hair dyeing	0.5%		- Contains alpha-naphthol
17	Sodium nitrite	Rust inhibitor	0.2%	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Rust inhibitor	0.3%		
19	Phenol and its alkali salts	Soaps and shampoos	1% calculated as phenol		- Contains phenol
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0.5% calculated as quinine base (b) 0.2% calculated as quinine base		

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
22	Resorcinol (1)	(a) Oxidizing colouring agent for hair dyeing 1. General use 2. Professional use (b) Hair lotions and shampoos	(a) 5% (b) 0.5%		(a) 1. - Contains resorcinol - Rinse hair well after application - Do not use to dye eyelashes and 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
23	(a) Alkali sulphides (b) Alkaline earth sulphides	(a) Depilatories (b) Depilatories	(a) 2% calculated as sulphur pH 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 the eyes

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
24	Water-soluble zinc salts with the exception of zinc-4-hydroxybenzenesulphonate 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
26	Ammonium monofluorophosphate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule, total F concentration must not exceed 0.15%.		- Contains ammonium monofluorophosphate
27	Sodium monofluorophosphate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains sodium monofluorophosphate
28	Potassium monofluorophosphate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains potassium monofluorophosphate
29	Calcium monofluorophosphate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains calcium monofluorophosphate
30	Calcium fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains calcium fluoride

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
31	Sodium fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains sodium fluoride
32	Potassium fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains potassium fluoride
33	Ammonium fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains ammonium fluoride
34	Aluminium fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains aluminium fluoride
35	Stannous fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains stannous fluoride
36	Hexadecyl ammonium fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains hexadecyl ammonium fluoride
37	3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride
38	NN'N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains NN'N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
39	Octadecenyl-ammonium fluoride	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains octadecyl-ammonium fluoride
40	Sodium fluorosilicate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains sodium fluorosilicate
41	Potassium fluorosilicate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains potassium fluorosilicate
42	Ammonium fluorosilicate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains ammonium fluorosilicate
43	Magnesium fluorosilicate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains magnesium fluorosilicate
44	1,3-Bis(hydroxymethyl)imidazolidine-2-thione	a) Hair care preparations b) Nail care preparations	a) Up to 2% b) Up to 2%	a) Prohibited in aerosols dispensers (sprays) b) The pH of the product as applied must be less than 4	- Contains 1, 3-bis (hydroxymethyl) imidazolidine-2-thione
45	Benzyl alcohol	Solvents, perfumes and flavouring			
46	6-Methylcoumarin	Oral hygiene products	0.003%		
47	Nicomethanol hydrofluoride	Oral hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this schedule, total F concentration must not exceed 0.15%		- Contains nicomethanol hydrofluoride

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4%		- Contains silver nitrate - Rinse the eyes immediately if product comes into contact with them
49	Selenium disulphide	Anti-dandruff shampoo	1%		- Contains selenium disulphide - Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr_y(OH)_yCl_z$ and the aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	<ul style="list-style-type: none"> ▪ 20% as anhydrous aluminium zirconium chloride hydroxide ▪ 5.4% as zirconium 	<ol style="list-style-type: none"> 1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10 2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0.9 and 2.1 3. Prohibited in aerosol dispensers (sprays) 	- Do not apply to irritated or damaged skin
51	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	<ul style="list-style-type: none"> ▪ Stabilizer for hydrogen peroxide in rinse-off hair care preparations. ▪ Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations. 	<ul style="list-style-type: none"> ▪ 0.3% calculated as base ▪ 0.03% calculated as base 		
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5% calculated as a % of ethanol and isopropyl alcohol		

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
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		
54	1-Phenoxypropan-2-ol	- Rinse-off products only - Prohibited in oral hygiene products	2%	As a preservative, see fourth schedule	
55	Lead acetate	Only for hair dyeing	0.6% calculated in lead		<ul style="list-style-type: none"> - Keep away from children. - Avoid all contact with the eyes. - Wash hands after use. - Contains lead acetate. - Do not use to dye eyelashes, eyebrows or moustaches. - If irritation develops, discontinue use.
56	Magnesium fluoride	Dental hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this schedule, total F concentration must not exceed 0.15%		<ul style="list-style-type: none"> - Contains magnesium fluoride

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
60	Fatty acid dialkanolamides		Maximum dialkanolamine content: 0.5%	<ul style="list-style-type: none"> - Do not use with nitrosating systems - Maximum dialkanolamine content : 5% (concerns raw materials) - Maximum N-nitroso-dialkanolamine content : 50 µg/kg - Keep in nitrite-free containers 	
61	Monoalkanolamines		Maximum dialkanolamine content: 0.5%	<ul style="list-style-type: none"> - Do not use with nitrosating systems - Minimum purity: 99% - Maximum secondary alkanolamine content: 0.5% (concerns raw materials) - Maximum N-nitroso-dialkanolamine content: 50 µg/kg - Keep in nitrite-free containers 	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
62	Trialkanolamines	(a) non-rinse-off products (b) other products	(a) 2.5%	(a) (b): - Do not use with nitrosating systems - Minimum purity: 99% - Maximum secondary alkanolamine content: 0.5% (concerns raw materials) - Maximum N-nitrosodialkanolamine content: 50 µg/kg - Keep in nitrite-free containers	
63	Strontium hydroxide	pH-regulator in depilatory products	3.5% calculated as strontium, max pH of 12.7		- Keep out of reach of children - Avoid contact with the eyes
64	Strontium peroxide	Rinse-off hair care preparations professional use	4.5% calculated as strontium in the ready-for-use preparation	All products must 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
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 products the concentrations of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C ₁₄ , or less must not exceed 0.1% (as benzalkonium chloride)	(a) Avoid contact with the eyes (b) Avoid contact with the eyes

ANNEX IV

Regulation 6(1)(c)

LIST OF DYES, PIGMENTS AND COLOUR ADDITIVES

TABLE 1 – DYES SUITABLE FOR USE IN ALL COSMETICS AND TOILETRY GOODS

(1)	(2)	(3)	(4)	(5)
Colour index no.	Colour	Colour index hue designation	Common name of the colour	FDA designation
42052	Blue	Acid Blue 5	Patent Blue NA	-
42090	Blue	(Acid Blue 9 Food Blue 2	Brilliant Blue FCF	FD & C Blue No. 1
73015	Blue	(Acid Blue 74 Food Blue 1	Indigocarmine	FD & C Blue No. 2
42053	Green	Food Green 3	Fast Green FCF	FD & C Green No. 3
42085	Green	(Acid Green 3 Food Green 1	Guinea Green B	-
42095	Green	(Acid Green 5 Food Green 2	Light Green SF Yellowish	-
45430	Red	(Acid Red 51 Food red 14	Erythrosine	FD & C Red No. 3
12085	Red	Pigment Red 4	Flaming Red	D & C Red No. 36
12150	Red	Solvent Red 1	-	-
14700	Red	Food Red 1	Ponceau SX	FD & C Red No. 4
15850	Red	Pigment Red 57	Lithol Rubin B	D & C Red No. 6
15850	Red	Pigment Red 57	Lithol Rubin BCA	D & C Red No. 7
15880	Red	Pigment Red 63	Lake – Bordeau B	D & C Red No. 34
60725	Violet	Solvent Violet 13	Alizurol Purple SS	D & C Violet No. 2
15985	Yellow	Food Yellow 3	Sunset Yellow FCF	FD & C Yellow No. 6
19140	Yellow	(Acid Yellow 23 Food Yellow 4	Tartrazine	FD & C Yellow No. 5
47005	Yellow	Food Yellow 3 Food Yellow 13 Solvent Yellow 2	Quinoline Yellow WS	D & C Yellow No. 10

**TABLE 2 –DYES SUITABLE FOR USE IN COSMETICS AND TOILETRY GOODS
APPLIED EXTERNALLY**

(1)	(2)	(3)	(4)	(5)
Colour index no.	Colour	Colour index hue designation	Common name of the colour	FDA designation
20470	Black	Acid Black 1	Naphthol Blue Black	-
42045	Blue	(Acid Blue 1 Food Blue 3)	-	-
42090	Blue	(Acid Blue 9 Food Blue 2)	Alphazurine FG	D & C Blue No. 4
44045	Blue	Solvent Blue 4	-	-
61530	Blue	Acid Blue 27	Alizarin Astrol B	-
42100	Green	Acid Green 9	Acid Fast Green	-
61565	Green	Solvent Green 3	Quinazarine Green SS	D & C Green No. 6
12120	Red	Pigment Red 3	Toluidine Red	-
12350	Red	Pigment Red 18	Deep Red (Maroon)	-
13058	Red	Pigment Red 100	Alba Red	-
15500	Red	Pigment Red 50	Lake Red D	-
15500	Red	Pigment Red 50	Lake Red DBA	-
15500	Red	Pigment Red 50	Lake Red DCA	-
15620	Red	Acid Red 88	-	-
15800	Red	Pigment Red 64	Brilliant Lake Red R	D & C Red No. 31
16150	Red	(Acid Red 26 Food Red 5)	Ponceau 2 R	-
16155	Red	Food Red	Ponceau 3 R	-
17200	Red	(Acid Red 33 Food Red 12)	-	D & C Red No. 33
26100	Red	Solvent Red 23	Toney Red	D & C Red No. 17
26125	Red	Solvent Red 27	Oil Red OS	-
45425	Red	Acid Red 95	Erythrosine Yellowish NA	D & C Orange No. 11
45425	Red	Acid Red 95	Erythrosine Yellowish K	-
45457	Red	Solvent Red 46	Bluish Orange TR	-
58000	Red	Mordant Red 11	Alizarin	-
60730	Violet	Acid Violet 43	-	-

(1)	(2)	(3)	(4)	(5)
Colour index no.	Colour	Colour index hue designation	Common name of the colour	FDA designation
10316	Yellow	(Acid Yellow 1 Acid Yellow 1	-	Ext D & C Yellow No. 7
11680	Yellow	Pigment Yellow 1	-	-
18820	Yellow	Acid Yellow 11	-	-
42350A	Yellow	Acid Yellow 73	-	D & C Yellow No. 7
45350	Yellow	Acid yellow 73	-	D & C Yellow No. 8
12075	Orange	Pigment Orange 5	Permanent Orange R	D & C Orange No. 17
14600	Orange	Acid Orange 20	-	-
15510	Orange	Acid Orange 7	Orange II	D & C Orange No. 4
16230	Orange	(Acid Orange 10 Food Orangen4	Orange G	-
20170	Orange	Acid Orange 24	Resorcin Brown	-
45371	Orange	Solvent Orange 18	Dibromodiiiodofluorescei n	-
45456	Orange	Solvent Orange 17	Orange TR	-

Note:

When the dyes are used for manufacture of:-

- (a) lipsticks, they shall be restricted to 6 per cent, maximum (pure, dry basis)
- (b) mouth washes and dentifrice, they shall be restricted to a maximum of 0.75 mg ingestion per day.

TABLE 3 – Permitted pigments and Colour additives

Pigments and colour additives (1)	Use*			Maximum Permissible limit for:		
	Lipstick (2)	External (3)	Area of the eye (4)	Lead mg/kg (5)	Arsenic mg/kg (6)	Mercury Mg/kg (7)
Aluminium benzoate	P	P	-	20	2	-
Aluminium hydroxide	P	P	P	20	2	-
Aluminium powder	-	P	P	20	3	1
Aluminium stearate	P	P	P	20	2	-
Annate	P	P	P	10	3	-
Barium sulfate (blanc fixe)	P	P	-	20	2	-
Bentonite	P	P	P	20	2	-
Bismuth oxychloride	P	P	P	20	3	1
Bone black	-	P	P	20	2	-
Bronze powder	P	P	P	20	3	1
Calcium carbonate	P	P	P	20	2	-
Calcium sulfate	-	P	-	20	2	-
Caramel	P	P	P	10	3	0.1
Carmine	P	P	P	10	1	-
Carotene	P	P	P	10	3	-
Charcoal	-	P	P	20	2	-
Chlorophyll copper complex	-	P	-	20	2	-
Chlorophyllin copper complex	-	P	-	20	2	-
Chromium hydroxide green	-	P	P	20	3	1
Chromium oxide green	-	P	P	20	3	1
Cochineal	P	P	-	10	1	-
Cornstarch	P	P	P	20	2	-
Copper powder	P	P	P	20	3	1
Dihydroxy acetone	-	P	-	20	3	-
Ferric ammonium ferrocyanide	-	P	P	20	3	1

*p indicates permitted

Pigments and colour additives (1)	Use*			Maximum Permissible limit for:		
	Lipstick (2)	External (3)	Area of the eye (4)	Lead mg/kg (5)	Arsenic mg/kg (6)	Mercury Mg/kg (7)
Ferric ferrocyanide	-	P	P	20	3	1
Gold	-	P	P	20	2	-
Graphite	-	P	P	20	2	-
Gunine (Pearl essence)	P	P	P	20	3	1
Guaiazulene	-	P	-	20	3	1
Iron oxides	P	P	P	10	3	3
Kaolin	P	P	P	20	2	-
Lampblack	P	P	P	20	2	-
Lithium stearate	-	P	-	20	2	-
Magnesium aluminium silicate	-	P	P	20	2	-
Magnesium carbonate	-	P	-	20	2	-
Magnesium oxide	-	P	-	20	2	-
Magnesium stearate	-	P	P	20	2	-
Magnesium trisilicate	-	P	-	20	2	-
Manganese violet	P	P	P	20	3	1
Mica	P	P	P	20	3	1
Pyrophyllite	-	P	-	20	3	-
Saffron	P	P	P	20	2	-
Silicon dioxide (silica)	P	P	P	20	2	-
Silk, powdered	P	P	P	20	2	-
Talc	P	P	P	20	3	-
Tin oxide	-	P	-	20	2	-
Titanium dioxide	P	P	P	10	1	1
Turmeric (<i>Curcuma longa</i>)	P	P	P	20	2	-
Ultramarine blue	-	P	P	20	3	1
Ultramarine green	-	P	P	20	3	1
Ultramarine pink	-	P	P	20	3	1
Ultramarine red	-	P	P	20	3	1
Ultramarine violet	-	P	P	20	3	1
Zinc oxide	P	P	P	20	3	1
Zinc stearate	-	P	P	20	2	-

*p indicates permitted

In addition to Table 3, pigments and colour additives which shall be considered suitable for use in:-

- (a) Hair dyes are Bismuth citrate and henna. The maximum permissible limits for lead and arsenic shall be 20 mg/kg and 3mg/kg respectively, maximum permissible limit for mercury in bismuth citrate shall be 1mg/kg.
- (b) finger nail polish is silver. The maximum level of silver shall not exceed 1 per cent of the final product.

ANNEX V

Regulations 6(1) (d)

LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN SUBJECT TO RESTRICTIONS

The substances marked with the symbol (+) may also be added to cosmetic products in concentration other than those laid down in this schedule for other purposes apparent from the labelling of the products, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos.

The concentration of the substance, when it is used as a preservative, in a product may not exceed the limit set out in column c. Where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Other requirements are specified in column d.

In this schedule-

“Salts” is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium, and ethanolamines; salts of the anions chloride, bromide, sulphate and acetate.

“Esters” is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

In column b, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

All finished products containing formaldehyde or any substances named in this schedule which release formaldehyde must be labelled with the warning “contains formaldehyde” where the concentration of formaldehyde in the finished product exceeds 0.05 percent.

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Benzoic acid, its salts and esters(+)	0.5% (expressed as acid)		
2	Propionic acid and its salts (+)	2% (expressed as acid)		

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
3	Salicylic acid and its salts (+)	0.5% (expressed as acid)		
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts (+)	0.6% (expressed as 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 (1)
5	Formaldehyde and Para-formaldehyde (+)	0.2% (except for products for oral hygiene) 0.1% (products for oral hygiene) expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	
7	Biphenyl-2-ol (o-phenylphenol) and its salts (+)	0.2% expressed as phenol		
8	Pyrithione zinc (INN) (+)	0.5%	Authorized in products rinsed off, forbidden in products for oral hygiene	
9	Inorganic sulphites and hydrogensulphites (+)	0.2% expressed as free SO ₂		
10	Sodium iodate	0.1%	Rinse-off products only	
11	Chlorobutanol (INN)	0.5%	Prohibited in aerosol dispensers (sprays)	Contains chlorobutanol
12	4-Hydroxybenzoic acid its salts and esters (+)	0.4% (acid) for 1 ester; 0.8% (acid) for mixtures		

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
		of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydroacetic acid) and its salts	0.6% (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt (+)	0.5% (expressed as acid)		
15	3,3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0.1%		
16	Thiomersal (INN)	0.007% (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	Contains thiomersal
17	Phenylmercuric salts (including borate)	0.007% (of Hg) If mixed with other authorized mercurial compounds, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	Contains phenylmercuric compounds
18	Undec-10-enoic acid and salts (+)	0.2% (acid)		

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
19	Hexetidine (INN) (+)	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	
22	2,4-Dichlorobenzyl alcohol (+)	0.15%		
23	Triclocarban (INN) (+)	0.2%	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene less than 1 ppm; 3,3',4,4'-Tetrachloroazoxybenzene less than 1 ppm	
24	4-Chloro-m-cresol (+)	0.2%	Prohibited in products intended to come into contact with mucous membranes	
25	Triclosan (INN) (+)	0.3%		
26	4-Chloro-3,5-xylenol (+)	0.5%		
27	3,3'-Bis(1-hydroxymethyl-2,5-dioxoimidazolidin-4-yl)-1,1'-	0.6%		

Referenc e Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
	methylenediurea ("Imidazolidinyl urea") (+)			
28	Poly(1-hexamethylenebiguanide hydrochloride (+)	0.3%		
29	2-Phenoxyethanol (+)	1.0%		
30	Hexamethylenetetramine (+) (methenamine) (INN)	0.15%		
31	Methenamine 3-chloroallylochloride (INNM)	0.2%		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl) 3,3-dimethylbutan-2-one (+)	0.5%		
33	1,3-Bis(hydroxymethyl)-5,5- dimethylimidazolidine-2,4-dione (+)	0.6%		
34	Benzyl alcohol (+)	1%		
35	1-Hydroxy-4-methyl-6(2,4,4- trimethylpentyl)2-pyridon and its monoethanolamine salt(+)	1% 0.5%	Products rinsed-off For other products	
36	1,2-Dibromo-2,4-dicyanobutane	0.1%	Not to be used in cosmetic sunscreen products at a concentration exceeding 0.025%	
37	6,6-Dibromo-4,4-dichloro-2,2'- methylene-diphenol:Bromochlorophen) (+)	0.1%		

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
38	4-Isopropyl-m-cresol	0.1%		
39	Mixture of 5-Chloro-2-methyl-isothiazol-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-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one)		
40	2-Benzyl-4-chlorophenol (Chlorophene)	0.2%		
41	2-Chloroacetamide	0.3%		- Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0.3% expressed as chlorhexidine		
43	1-Phenoxypropan-2-ol	1.0%	Only for rinse-off products	
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (+)	0.1%		
45	4,4-Dimethyl-1,3-oxazolidine	0.1%	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl)-1,3-dioxo-2,5-	0.5%		

Referenc e Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
	imidazolinidyl-4)-N'-(hydroxymethyl) urea			
47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxy- benzoate (+))	0.1%		
48	Glutaraldehyde (Pentane-1,5-dial)	0.1%	Prohibited in aerosols (sprays)	- Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)
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	
50	3-(p-Chlorophenoxy)-propane-1,2-diol (chlorphenesin)	0.3%		
51	Sodium hydroxymethylamino acetate (Sodium hydroxymethylglycinate)	0.5%		
52	Silver chloride deposited on Titanium dioxide	0.004% calculated as AgCl	20% AgCl (w/w) on TiO ₂ Prohibited in products for children under three years of age, in oral hygiene products	

Referenc e Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
			and in products intended for application around the eyes and on the lips	
53	Benzethonium chloride	0.1%	Rinse-off products only	
54	Benzalkonium chloride, bromide and saccharinate	0.1% calculated as Benzalkonium chloride		- Avoid contact with the eyes
55	Benzylhemiformal	0.15%	Only for products to be removed by rinsing	
56	3-Iodo-2-propynylbutylcarbamate	0.05%	<ol style="list-style-type: none"> 1. Not to be used for oral hygiene and lip care products 2. If the concentration in products intended to remain on the skin exceeds 0.02% add the phrase: Contains iodine 	- Contains iodine

ANNEX VI

Regulations 6(1) (f)

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT UNDER SPECIFIED CONDITIONS

In this Schedule, the matters specified in column 3, 4 and 5 which apply to a particular substance are those set out to the right of its name as mentioned in column 2. The concentration of the substance in a product may not exceed the limit specified in column 3. Where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Required information is specified in column 4. In column 3 of this Schedule, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

Names which appear in square brackets in column 2 are the International Nomenclature Cosmetic Ingredient names of the substances in question given in the inventory of ingredients employed in cosmetic products.

(1)	(2)	(3)	(4)
Reference number	Name of substance	Maximum concentration of substance in product	Required information
1.	4-Aminobenzoic acid [PABA]	5 per cent	-
2.	<i>N,N,N</i> -Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulphate [Camphor benzalkonium methosulfate]	6 per cent	-
3.	Homosalate (INN)	10 per cent	-
4.	Oxybenzone (INN) [Benzophenone-3]	10 per cent	Contains oxybenzone (Not required when concentration is less than 0.5 per cent and when the substance is only intended to protect the product)
5.	2-Phenylbenzimidazole-5-sulphonic acid [Phenylbenzimidazole sulfonic acid] and its potassium, sodium and triethanolamine salts	8 per cent (expressed as acid)	-
6.	3,3`-(1,4-	10 per cent	-

	Phenylenedimethylene)-bis (7,7-dimethyl-2-oxobicyclo[2.2.1]hept-1-ylmethanesulphonic acid) [Terephthalylidene dicamphor sulfonic acid] and its salts	(expressed as acid)	
7.	1-(4- <i>tert</i> -Butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione (Avobenzone(INN))[Butyl methoxy dibenzoylmethane]	5 percent	-
8.	α -(2-Oxoborn-3-ylidene) toluene -4-sulphonic acid [Benzylidene camphor sulfonic acid] and its salts	6 percent (expressed as acid)	-
9.	2-Ethylhexyl 2-cyano-3,3-diphenylacrylate [Octocrylene]	10 percent (expressed as acid)	-
10.	Polymer of N-[(2 and 4)-[(2-oxoborn-3-ylidene)methyl] benzyl] acrylamide [Polyacrylamidomethyl benzylidene camphor]	6 percent	-
11.	2-Ethylhexyl 4-methoxycinnamate [Octyl methoxycinnamate]	10 percent	-
12.	Ethoxylated ethyl-4-aminobenzoate [PEG-25 PABA]	10 percent	-
13.	Isopentyl 4-methoxycinnamate [Isoamyl <i>p</i> - methoxycinnamate]	10 percent	-
14.	Tris (2-ethylhexyl) 4,4'-(1,3,5-triazine -2,4,6-triyltriimino)tribenzoate [Octyl triazone]	5 percent	-
15.	2-(2H-Benzotriazol-2-yl)-4-methyl-6-[2-methyl-3-[1,3,3,3-tetramethyl-1-(trimethylsilyloxy)disiloxan-1-yl]propyl]phenol [Drometrizole trisiloxane]	15 percent	-
16.	Bis (2-ethylhexyl)4,4'-[6- <i>tert</i> -butylcarbamoylanilino)-1,3,5-triazine-2,4-diyl]diimino]dibenzoate	10 percent	-
17.	3-(4-Methylbenzylidene) bornan-2-one[4-	4 percent	-

	Methylbenzylidene camphor]		
18.	3-Benzylidenebornan-2-one[3-Benzylidene camphor]	2 percent	-
19.	2-Ethylhexyl salicylate [Octyl salicylate]	5 percent	-
20.	2-Ethylhexyl 4-dimethylaminobenzoate [Octyl dimethyl PABA]	8 percent	-
21.	2-Hydroxy-4-methoxybenzophenone -5-sulfonic [Benzophenone-4] and its sodium salt [Benzophenone -5] (Sulisobenzone (INN) and Sulisobenzone sodium (INN.M))	5 percent (expressed as acid)	-
22.	2-2'-Methylenebis [6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol]	10 percent	-
23.	Disodium 2,2'-(1,4-phenylene) bis (1 <i>H</i> -benzimidazole-4,6-disulfonate)	10 percent (expressed as acid)	-
24.	5,5'-Bis (2-ethylhexyloxy)-2,2'-(6- <i>p</i> -methoxyphenyl-1,3,5-triazine-2,4-diyl)diphenol	10 percent	-
25.	α -(Trimethylsilyl)- ω -(trimethylsilyloxy)poly-[dimethyl)silylene]-co-[oxy(methyl)(2-[<i>p</i> -[2,2-bis(ethoxycarbonyl)-vinyl]-phenoxy]- 1-methylene ethyl)silylene-co-[oxy(methyl)(2-[<i>p</i> -[2,2-bis(ethoxycarbonyl)vinyl]-phenoxy]prop-1-enyl)silylene]where there are usually 60 polymeric units, of which the first part of the copolymer provides 56 (Dimethicodiethyl/Benzalma ionate)	10 percent	-
26.	Titanium dioxide	25 percent	-