Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Cosmetics and Sanitary Items Directive

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Addis Ababa

Contents

Preamble

WHEREAS, protection of the public from adulterated, misbranded or otherwise unsafe cosmetic products and sanitary items is one of the authority's public health responsibilities;

WHEREAS, it is found essential to require medicated cosmetic and functional cosmetic to pass through a registration process and confirm their safety and effectiveness before being authorized for marketing in the country;

WHEREAS, it is found very important to regulate and control the presence of prohibited ingredients or harmful concentration of restricted ingredients in cosmetic products is detrimental to health;

WHEREAS, it is necessary to take appropriate administrative and legal actions against violating products, entities and individuals;

WHEREAS, the existing regulatory framework in relation to cosmetic and sanitary items is found to be incomprehensive and unpredictable;

WHEREAS, it is believed to be valuable to provide importers, exporters and distributors with minimum regulatory information before their products legally make its way to the market;

NOW, THEREFORE, this directive is issued in accordance with Article 55 (3) of the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009 and Article 98 of the Food, Medicine and Healthcare Administration and Control Regulation No. 299/2014.

PART ONE
GENERAL

1. Short title

This directive may be cited as "Cosmetics and Sanitary Items Directive No.24./2014."

2. Definitions

Without prejudice to the definitions provided under Proclamation No. 661/2009 and Regulation No.299/2014, in this directive, unless the context otherwise requires:

1) "Cosmetics" includes ordinary, medicated and functional cosmetic;
2) "Ordinary Cosmetic" means any substance or preparation intended to be applied to external part of a human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. This shall also include any substance intended for use as component of a cosmetic;
3) "Medicated cosmetic " means any substance or preparation containing active drug ingredients which helps for preventing, healing or treating skin diseases or disorders, or having a therapeutic claim, and intended to be rubbed, poured, sprinkled or sprayed on or introduced in to or otherwise applied to external part of a human body or part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and substances intended for use as a component for such substances; It shall include antiseptics and disinfectants;
4) "Functional cosmetic " means any substance or preparation having whitening, anti-wrinkling or anti-aging effect; any substance or preparation intended for clarification or bleaching of the skin or a substance or preparation with primary sunscreen effect having Sun Protection Factor (SPF) greater than four, or

secondary sunscreen effect having Sun Protection Factor (SPF) greater than twenty;

5) "Claim" means any message or presentations including pictorial, graphic, symbolic or any form of representation, which states, suggests or implies that a product has particular characteristics relating to its origin, function, nature, composition or any other characteristics;
6) "Whitening agent" means a cosmetic product that is designed to whiten the skin tone;
7) "Anti-wrinkling agent" means a cosmetic that is designed to minimize the appearance of the lines in the face or body;
8) "Sunscreen" means a cosmetic product that is designed to protect the skin from the Ultra Violate A (UVA) and Ultra Violate B (UVB) rays of the sun or to develop natural looking tanning of the skin;
9) "Primary sunscreens" means a sunscreen cosmetic intended for therapeutic purpose;
10) "Secondary sunscreens" means a sunscreen cosmetic having a primary purpose of moisturizing and containing a sunscreen for secondary purposes;
11) "Ultra Violet (UV) filter" means a substance which is added to a sunscreen cosmetic for the purpose of filtering UV rays to protect the skin;
12) "Mouth washes" means a liquid or spray oral hygiene products for prevention of mouth odor or breath fresheners;
13) "Body deodorizer" means a preparation for external use for prevention of body odor;
14) "Heat rashes powder" means a powder for external use for prevention of heat rashes;
15) "Dentifrice" includes tooth pastes, tooth powders, tooth liquids containing hydrogen peroxide, fluoride, precipitated calcium and silicon dioxide;
16) "Bath preparation" means a product for external use for bath which may contain soap as body deodorant or a skin disease assisting treatment;
17) "Laundry soap" means a product consisting primarily of an alkali salt of fatty acid;

18) "Sanitary item" means any preparation used in the maintenance of cleanliness of human, household, and includes pads, diapers, tampons, dentifrices, sweat-bands and detergents;
19) "Detergent" means any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, molded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes;
20) "Auxiliary washing preparation" means a product intended for soaking (pre-washing), rinsing or bleaching clothes, household linen, etc;
21) "Laundry fabric-softener" means a product intended to modify the feel of fabrics in processes which are to complement the washing of fabrics;
22) "Surfactant" means any organic substance and/or preparation used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or micro-emulsions and/or micelles, and of adsorption at water-solid interfaces;
23) "Biodegradability" means the structural change or transformation of a surfactant by microorganisms results in the loss of its surface active properties due to the degradation of the parent substance and consequential loss of the surface active property;
24) "Ultimate biodegradability" means the level of biodegradability achieved when the surfactant is totally used by microorganisms in the presence of oxygen resulting in its breakdown to carbon dioxide, water, and mineral salt of any other element present;
25) "Misbranded cosmetic " means a regulated product under this directive which is falsely labeled, having misleading labeling or if it does not bear the required labeling information in accordance with this directive and/or other applicable laws;
26) "Adulterated cosmetic " means a regulated product under this directive which bears or contains any poisonous or deleterious substance that may render it injurious to user; a product consisting in whole or in part of any filthy, putrid, or

decomposed substance; a product consisting a substance other than its content or by substituting its content in whole or in part by such other substance or by storing or manufacturing it under unsanitary conditions whereby it may have been contaminate;

27) "Label" means any material which is written, printed, graphic matter or affixed to a packing material which provides the necessary information about regulated product under this directive, and includes an insert;
28) "Product" means cosmetic and sanitary items as defined under this directive;
29) **"**Expiration date" means the date after the product will be expired and should not be used anymore;
30) "Period after Opening" (PAO) means the time after which the product may cease to comply with the general safety requirement;
31) "Special shop" means a shop specially designed to sold or distribute cosmetics in self contained or separated area within the supermarket or other firms; and
32) "Authority" means the Ethiopian Food, Medicine and Healthcare Administration and Control Authority.

3. Objectives

The objectives of this directive shall be to:

1) protect the public from adulterated, mislabeled or otherwise unsafe cosmetics and sanitary items;
2) ensure safety and effectiveness of medicated cosmetic and functional cosmetic; and
3) Provide guidance for importers, exporters and distributors with regulatory information concerning minimum requirements in the marketing of regulated products under this directive.

4. Scope

This directive shall be applicable on all products and raw materials of cosmetic and sanitary items.

5. Principles

1) In order to market regulated products exporters, importers, and distributors shall have a certificate of competence issued by the Authority.
2) Notwithstanding to sub-article (1) of this article, medicated cosmetic and functional cosmetic products shall also be registered in accordance with this directive. Where the product is to be imported, a pre-import permit granted by the Authority shall accompany the product.
3) Subject to applicable provisions of this directive, ordinary cosmetic and sanitary items may be imported without prior registration.
4) Without prejudice to the preceding provisions, regulatory requirements in relation to cosmetics and sanitary items shall be enforced through inspection at ports of entry, storage, and during and after distribution.
5) Appropriate administrative measures shall be taken against violating products.
6) Importer and distributor, as appropriate, shall be responsible for the safety problems associated with their marketed products.

PART TWO
CERTIFIATE OF COMPETENCE

6. Requirements and issuance of a certificate of competence

1) Any person who wants to import, export, or wholesale a regulated product under this directive shall apply for a certificate of competence in accordance with ANNEX-I.

2) An exporter, importer, or distributor of regulated products applying for a certificate of competence under this directive shall fulfill minimum requirements in relation to location, building design and construction, materials and manpower as defined from Article 7 to Article 10 of this directive.
3) Where the applicant intends to operate trade in ordinary cosmetics together with medicated and function cosmetics, it shall fulfill particular requirements provided for medicated and functional cosmetics.
4) Notwithstanding to sub-article (1) of this article, and depending on the nature of the product, other appropriate factors may be considered in granting a certificate of competence.
5) In order to determine compliance with this directive, the Authority shall conduct an onsite inspection of the intended facility by at least two inspectors. Where inspection results find out one or more set requirements to be corrected, re-inspection may be carried out free of charge. However, an inspection beyond the second time may only be made against payment of service fee required by the Authority.
6) If the inspection result conducted under sub-article (5) of this article warrant granting of the certificate of competence, the Authority shall issue the same against payment of the prescribed service fee.

7. Location

1) The facility shall
   a) be self-contained
   b) be reasonably away from flood and swamp prone areas, offensive and waste disposal site;
   c) have basic infrastructures including road, electricity, and water;
2) The premise shall be free of conditions which might lead to contamination including excessive dust, foul odors, smoke, pest and insect infestations, airborne microbial and chemical contaminants, and other similar conditions.

8. Building design and construction

1) The store shall provide sufficient space for all activities carried out proportional to the amount of the products including a storage room, dispatch room, separate quarantine and rejected products storage room or area.
2) The store shall be constructed in such a way that it does not compromise the safety and quality of products.
3) The building shall be constructed with materials that do not affect the safety and quality of the product;
4) The storage room shall be separate or separately enclosed.
5) Floor of the storage room shall be made in cement, concrete, ceramic or similar materials; easily washable, free from cracks, be smooth and not convenient to harbor dirt and water.
6) Wall of the storage room shall be easily cleanable, free from cracks, and not convenient to harbor dirt.
7) The roof shall be constructed from materials that do not allow the entry of direct sun light and which do not adversely affect the temperature of the room.
8) Rooms shall be constructed in such a way to allow adequate air and light circulation.

9. Materials and equipments

1) Shelves or pallets shall be placed in such a way that they are at least 10cm away from the floor and 20cm away from the walls and 30cm from the ceiling. Each shelf shall be placed 50cm away from each other.
2) Depending on the climatic conditions of the area there shall be ventilator or air conditioner.
3) Any materials in the store having contact with the regulated product shall not compromise the safety and quality of products;
4) An enclosed waste bin, fire extinguisher and first aid kit shall be available.
5) Necessary safety materials for workers including glove and working cloths.

6) Where products that need refrigerator for their storage, it shall have refrigerator or cooling equipments.
7) Where the facility holds or distributes medicated and functional cosmetics, it shall have equipment to measure moisture and temperature.

10. Professional requirements

1) Any person engaged in import, export or distribution of regulated products under this directive shall have an adequate number and appropriate technical and other personnel.
2) For a person to engage in trade in medicated and functional cosmetics, the person who runs the business as technical personnel shall be druggist or pharmacist.
3) If the person wants to engage in trade in ordinary cosmetics alone or sanitary items, it shall have a person who completed at least grade 10 in accordance with the new education policy or grade 12 in accordance with the prior education policy as technical personnel.
4) The technical personnel described under sub-article (3) of this article shall be familiar with basic knowledge regarding the handling, storage, transportation, use, nature, content, side effects and other related character of the product.

11. Displaying certificate of competence

Original of the certificate of competence shall be placed in a conspicuous place where it can be easily seen by clients and regulatory officers.

12. Replacement of certificate of competence

Any person whose certificate of competence is damaged or lost may request replacement by submitting a signed and dated application to the Authority.

13. Change of address and technical personnel

No person may change location and technical personnel of the facility without notifying and securing the permission from the Authority.

14. Renewal of the certificate of competence

1) A certificate of competence shall be renewed between Hamle 1 and Nehase 30 of the Ethiopian calendar up on the confirmation of regulatory compliance through annual inspection, and payment of prescribed service fee.
2) If the certificate of competence is not renewed in accordance with sub-article (1) of this article, it shall be renewed with 50% increment penalty for each of the coming two months.
3) If the certificate of competence is not renewed in accordance with sub-article (2) of this article, the certificate of competence shall be considered cancelled.

PART THREE

ILLUSTRATIVE LIST OF COSMETICS AND REGISTRATION

15. Illustrative list of ordinary cosmetic

1) Ordinary cosmetic products shall include deodorants, skin washes, moisturizer, cleanser, cream, scrub, astringent, toner, lotion, toothpastes and gels that contain 1000 mg/kg or less of fluoride ion, mouthwashes that contain an antibacterial substance, mouthwashes that contain 220 mg/L or less of fluoride ion, primary sunscreen products where their SPF is less than four, moisturizers containing a sunscreen as a secondary purpose and those products listed under Annex-III of this directive.

2) The moisturizers containing a sunscreen as a secondary purpose expressed under sub-article (1) of this article shall meet the definition of secondary sunscreen product and shall not be water-resistant.
3) Any ordinary cosmetic product having a therapeutic claim shall be regulated as a medicated cosmetic and pass through the registration procedure required under this directive.

16. Illustrative list of medicated cosmetic

1) Medicated cosmetic includes antiperspirant, antidandruff preparations such as antidandruff shampoos, antidandruff hairdressings, antidandruff lotions, antidandruff oil, antidandruff creams; antibacterial skin cleansers, anti-acne products; toothpastes, mouthwashes, gels having 1000 mg/kg or more fluoride ion; antiseptics, disinfectants and intimate products.
2) For the purpose of this directive "antiperspirant" means a product that reduces the extent of sweating, with or without the presence of perfumes, as well as the occurrence unsightly sweat marks on clothing. These products serves as temporarily reducing the extent of normal sweating by modifying the organic function of sweat glands, minimizing body odors, and decreasing the occurrence of unsightly sweat marks on clothing.
3) For the purpose of this directive "intimate product" means personal products intended for soothing or lubricating the intimate part of human organ for sexual activity.
4) Notwithstanding to sub-article (1) of this article, antiperspirant preparations that derive their antiperspirant properties from inorganic salts such as aluminum, zinc or zirconium and indicated for hyperhydrosis or otherwise providing a more permanent effect or treat or mitigate a disorder shall be classified as medicine.

17. Illustrative list of functional cosmetic

Functional cosmetic is as defined under article 2(4) of this directive and include such products with anti-wrinkling, anti-aging, whitening, anti-hair loss products or sunscreen claims or ingredients.

18. Registration requirement

Any person who wants to market medicated cosmetic and functional cosmetic shall have its product registered in accordance with the following articles.

19. Administrative documents

1) Application for registration

a) A duly filled separate registration application shall be required for every product type and products with different ingredients or same products manufactured at different manufacturing sites. Application for the registration of medicated cosmetic or functional cosmetic shall be made in accordance with Annex-IV of this directive.

b) An applicant shall submit actual sample of the proposed product, its primary and secondary packaging materials and labeling information together with the hard and electronic copy of registration file.

c) The Authority may require the applicant additional information or samples for clarification during evaluation of the product.

d) If the applicant fails to submit written response for the information or documentation required under sub-article (1) (c) of this article within six months, or if the queries has been reissued for the third time and the applicant provide unsatisfactory responses, the application shall be deemed to be

withdrawn. An applicant whose application is rejected in accordance with this article may reapply for registration.

e) An applicant whose application is considered withdrawn in accordance with sub-article (1) (d) of this article may lodge new registration application.

f) The entire registration file shall be submitted in English or Amharic. Where original certificate are in other languages, copies shall be presented together with authenticated translation.

2) Good manufacturing practice, free sale certificate and manufacturer profile

a) Certificate of Good Manufacturing Practice (GMP) from local regulatory authority; and free sale certificate issued by competent organ in the country of origin and, authenticated by Ethiopian embassy or consulate shall be submitted.

b) In appropriate circumstances, internationally accepted certification or certificate of quality management system may be accepted in lieu of GMP.

c) Background information including year of establishment, development of the company since establishment, organo gram and full address of the manufacturer shall be submitted. Manufacturer profile may be omitted if the manufacturer is already registered with the Authority.

20. Technical documents

1) Chemical and analytical data for raw materials

a) Manufacturer shall indicate reference to each ingredients used for the preparation of the product to be registered. Reference may be made to the International Cosmetic Ingredient Dictionary (ICID), European Union Cosmetic Ingredients Compendium (EUCIC), or other compendiums accepted by the Authority.

b) If the reference and /or specification of an ingredient are in-house, the manufacturer shall submit definition of the ingredients, identification (both the method of identification and result obtained by the indicated method), method of manufacturing or preparation, and analytical data and test method for the raw materials.

c) All substances used in the preparation must be given in the qualitative and quantitative formula. This could be: active ingredients, preservatives, antioxidants, chelators, buffering agents, solvents and other additives.

d) The basic and minimum specifications active ingredient of medicated and functional cosmetic shall have include chemical identity, physical form, purity of the chemical, characterization of impurities or accompanying contaminants, solubility, partition coefficient(Log P_{ow}), additional relevant physical, microbiological and chemical specifications.

e) In addition to requirements mentioned under sub-article (1) (d) of this article, certificate of analysis should be submitted to provide full characterization of the test chemical.

2) Formulation data

a) Data on composition

Composition data shall indicate all the lists of ingredients, including the quantity and quality specification. The name used for and 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 Cosmetic, Toiletry, and Fragrance Association (CTFA) name, its European pharmacopoeia name, its international non-proprietary name as recommended by the World Health Organization, its Inventory of Existing Commercial Substance (INECS), International Union of Pure and Applied Chemistry (IUPAC) or Chemical Abstract Service (CAS) identification reference or its color index number.

b) Method of manufacture (preparation)

i. The method of manufacture shall show flow chart for the method of manufacture, concise description of the method of preparation mentioning the quality and quantity of the raw materials used including the final packaging and labeling procedures.
ii. Method of preparation including all physical, chemical, enzymatic, biotechnological and microbiological steps shall be clearly stated.
iii. Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated.

3) Data on method of analysis and specification of the finished product

a) Manufacturer of a regulated product under this chapter, where appropriate, shall mention relevant control parameter for the finished product and their limit of specification. The final product specification may indicate appearance (clarity, color, homogeneity and odor), consistency, particle size, pH, average weight or volume, microbiological limit and assay.
b) Method of analysis for the finished product shall indicate all the test method and specification. The test methods shall mention including the equipment, reagent and method.

4) Stability data

Stability data shall be submitted and it shall indicate:

a) the formulation;
b) minimum of two batch numbers and batch type;
c) date of manufacture;
d) expiry date or any comparable statement including, “use within …..years from the date of manufacture” or “best before …….’;
e) type and chemical nature of the packaging materials;

f) analytical methods that will quantitatively measure the characteristic structural and chemical properties of each active or functional ingredients of a dosage form and distinguish them from their degradation products so that active ingredient content can be measure;
g) initial and all subsequent results of chemical, physical and/or biological testing. The frequency of testing must be every three months including the initial for the first year and every six months for the second year and every year thereafter; and
h) summary of the study and storage recommendations based on the generated data.

5) Data demonstrating safety and efficacy

a) To determine the margin of safety for human use, relevant toxicity tests shall be submitted. Where appropriate, single dose toxicity, primary skin irritation, ocular or mucous membrane irritation test, skin sensitization, photo toxicity and photosensitivity, and repeated human irritation test shall be submitted.
b) For sunscreen products, SPF test method and expression of SPF shall be submitted.
c) For Whitening agents, in vivo tyrosine activity, in vitro melanin synthesis inhibition assay, and DOPA autoxidation test shall be submitted.
d) For anti-wrinkle products, cell proliferation assay, collagen synthesis assay, and elastase inhibition assay shall be submitted.
e) For fluoride containing tooth paste, enamel solubility reduction test, and fluoride enamel uptake test shall be submitted.

21. Notification of variation and re-registration

1) Where there is any variation of a registered medicated cosmetic and functional cosmetic after market authorization, the responsible person shall have the obligation

to notify of the variation to the Authority before marketing this product. For the purpose of this article, the "responsible person" means, an importer of the product.

2) A product registered in accordance with the preceding article shall be valid for five years. The authorized person shall have the obligation to apply for re-registration within 120 days before the due date. Re-registration requirements shall include current GMP certificate and a confirmatory letter that the method of manufacture or preparation is not changed.

PART FOUR
PACKAGING AND LABELLING

22. General

1) The packaging material shall be made out of substances, safe and suitable for its intended use and the product shall be packed in container which will safeguard its hygienic, safety and quality.
2) The immediate container of an ordinary cosmetic, medicated cosmetic and functional cosmetic shall be affixed or written on with a label bearing the following particulars in clearly legible and indelible letters at least in Amharic or English:

    a) Name of the product;
    b) Name and full address of the manufacturer, including country of origin;
    c) Form of the product;
    d) Intended use of the product;
    e) Instructions of use;
    f) Net content;
    g) List of ingredients;
    h) Batch or lot number;
    i) Precautions and warnings, where necessary; and
    j) Storage condition, as appropriate.

3) Expiry date, best before or period after opening or comparable terms shall be clearly written on the immediate container of medicated cosmetic and functional cosmetic product.
4) Expiry date best before or period after opening or comparable terms shall be clearly written on immediate container of the product, where necessary.
5) Notwithstanding to sub-article (4) of this article, expiry date shall be specified for an ordinary cosmetic whose shelf life is thirty months or less.
6) Period after opening (PAO) may be used when, after opening, the deterioration of the product may lead to harm to the consumer. PAO symbol or term may not be necessary where no physical opening of the product as in the case of products presented in containers where there is no possibility of contact between the product in the container and the external environment (e.g. aerosols), and the product is a single-use item.
7) Where the size, shape or nature of the container or package does not permit all the information provided under this directive 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 indicating the name of the product, batch or lot number and expiry date, where appropriate.
8) All ingredients on the label of the product shall be listed in accordance with the following sub-articles:
   a) List of ingredients, which will be present in the final product including both the quantity and quality specification. The name used for and 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 World Health Organization, its International Union of Pure and Applied Chemistry (IUPAC) or Chemical Abstract Service (CAS) Identification reference or its color index number.
   b) In case of decorative cosmetic marketed in a range of color shades, all coloring 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 that are present at a concentration of 1% or less and all coloring agents, regardless of their concentration may be listed in random order after the ingredients that are present at a concentration of more than 1%.

9) Liquid or oral hygiene products (e.g. Mouth washes, fresheners) and all cosmetic vaginal products (eg. douches, tablets) must be packed in a tamper resistant package. The feature may involve the immediate or outer container or both. The package must also bear a prominently placed statement alerting the consumer to the tamper-resistant feature. This statement must remain unaffected if the tamper resistant feature is breached or missing.
10) In addition to the general requirement for labeling, a hair dye product label should indicate the categories of hair dye (Permanent, Semi permanent or temporary hair colors), and coal tar containing hair dye product label shall bear direction for patch test and should bear the following caution, "This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."
11) Any SPF or equivalent category description shall be disclosed on the label of sunscreen products.
12) The SPF or equivalent category description disclosed on the label shall be determined by acceptable International Standards for the precise formulation.
13) Label claims must be true, verifiable and accurately communicate product features, characteristics and performance. In particular, the following statements are prohibited:

a) "Recommended by doctors" or any other word or words or pictorial representation implying that medical practitioners in general recommend its use.
b) A claim that conveys that the product possesses health-giving properties shall, unless such word, indication or claim can be scientifically substantiated.

14) Where an ordinary cosmetic product is prepared for use for a specific facility (such as hotels and other hospitality institutions), and the name of the institution is affixed or written on the product, labeling requirements provided under this article may not be applicable.

23. Leaflets

1) Medicated cosmetic and functional cosmetic shall have leaflets or package insert accompanying the product.
2) Every leaflet or package insert of functional and medicated cosmetic shall at least include the following particulars in clearly legible and indelible letters at least in Amharic or English:

   a) Name of the product;
   b) Form of the product;
   c) Intended use of the product;
   d) Instructions of use of the product;
   e) Net content given by weight or volume, in metric system;
   f) Name and full address of the manufacturer, including country of origin;
   g) List of ingredients;
   h) Precautions and warnings;
   i) Its adverse effect ;
   j) Storage condition where applicable; and
   k) Pregnancy and lactation related issues.

24. Import requirement

1) In order to get port clearance, the following documents shall be required:
   a) Application letter;
   b) Certificate of competency;

c) Certificate of origin;
d) Copy of certificate of analysis for medicated cosmetic and functional cosmetic
e) Invoice;
f) Packing list;
g) Original free-sale certificate for the ordinary cosmetic from the appropriate government organ per manufacturer during the first time of importation;
h) Airway bill or bill of loading;
i) Pre-import permit for medicated cosmetic and functional cosmetic;
j) Registration certificate for medicated cosmetic and functional cosmetic; and
k) Manufacturer's declaration of absence of prohibited substances and compliance with the content lists of restricted substances for the ordinary cosmetic.

2) Where any original certificate is in language other than English or Amharic, copies shall be presented together with certified translation.
3) Notwithstanding to sub-article (1) (g) of this article, where free sale certificate is not customary to be issued in the country of origin, such may be certified by the Authority from Embassy, consulate or appropriate government organ of the country of origin.
4) An ordinary cosmetic shall only be imported if their label is in accordance with this directive.

25. Storage, transportation and distribution

1) Applicable safety standards of detergents, ordinary cosmetic, medicate cosmetic, and functional cosmetic shall be observed during storage, handling and transportation.
2) Products shall be stored in their appropriate condition according to instructions on the label.
3) Deteriorated, expired, and damaged products shall be stored separately from products until disposal.

4) Every effort shall be made to make sure products are stored in such a way that it supports the first expired first out (FEFO) and first in first out (FIFO) principles.
5) Inspection of a regulated detergents and cosmetic facility shall be carried out based on identified adverse event, complaints or agency self-initiated compliance investigation.
6) Importer or distributor of medicated cosmetic and functional cosmetic may only distributes products for retails.
7) For the purpose of this article, "retailer" includes drug shop, pharmacy and special shop.
8) Medicated cosmetic and function cosmetic shall be held by trained professional in the field and an authorized facility.

26. Import requirements for detergent and cosmetics raw materials

1) **Labeling**

Importers of raw materials for detergent, ordinary cosmetic, medicated cosmetic and functional cosmetic shall at least include the following particulars on the primary container in clearly legible and indelible letters at least in Amharic or English

a) Name of the product;

b) Name and full address of manufacture, supplier, distributor, importer, as appropriate

c) Batch or lot number, where appropriate;

d) expiry date, where necessary;

e) Precautions and warnings, where necessary; and

f) storage condition, where necessary.

2) **Required documents**

An importer of raw materials intended for use in the production or use of detergent, cosmetic, medicated cosmetic and functional cosmetic shall submit

a) Application letter;
b) Certificate of origin;
c) Safety data sheet and/or certificate of analysis;
d) Invoice;
e) packing list;
f) pre-import permit for active raw materials intended for medicated cosmetic and functional cosmetic; and
g) Airway bill or bill of loading.

27. Export

Depending on requirements of the country of destination and mandate of the Authority, required regulatory documents may be issued by the Authority to exporters.

28. Prohibitions and restriction of ingredients

1) An importer shall take every effort to make sure products introduced in to this country do not contain prohibited ingredients or violate restriction of ingredients as provided from Annex V to Annex-X of this directive.
2) Where a product is found suspicious to have or confirmed to have prohibited or restricted ingredients, the Authority may take appropriate administrative measures.
3) A product intended to be placed in the market shall not contain any of the following:

a) A prohibited ingredient as provided in Annex V of this directive;

b) Any substance listed in column b of Annex VI of this directive unless the requirements in column c, d, e and f of that annex in relation to that substance are satisfied;
c) Any coloring agent which is not listed in Annex VII of this directive;
d) Any preservative listed in column 2 of Annex VIII of this directive unless the requirements in column 3, 4, and 5 of the Annex in relation to that preservative are satisfied;
e) Any preservative which is not listed in Annex VIII of this directive;
f) Any UV filter listed in column 2 of Annex IX of this directive unless the requirements in column 3 and 4 of the Annex are satisfied.

PART FIVE
SANITARY ITEMS

29. Biodegradability requirement of surfactants in detergents

1) Manufacturers placing detergent products on the market shall conform biodegradability of surfactants used in these products obtain from their surfactant suppliers, written confirmation (on Material Safety Data Sheet or on a specific document or analysis certificate) that the surfactants used may be placed on the market without further limitation due to their ultimate biodegradability.
2) The ultimate biodegradability criteria shall apply to all types of surfactants (anionic, non-ionic, cationic and amphoteric). The criteria for ultimate biodegradability shall be 60% in 28 days. Manufacturers shall hold, as the disposal of the authority, a technical file with the results for the test of ultimate biodegradability.
3) In the case of surfactants that do not pass the ultimate biodegradability test, the technical file shall also contain the results of the primary biodegradability test and the complementary risk assessment. The criteria for primary biodegradability are 80% in 28 days. If the criteria for ultimate biodegradability are not fulfilled, derogations are possible only for certain surfactants in detergents used in industrial or institutional sectors in applications.

4) For the purpose of sub-article (3) of this article, written confirmation shall be obtained that surfactants fulfill the pass criterion of 80% for primary biodegradability and a derogation issued by a competent public authority must be available for the surfactant in question.

30. Labeling of sanitary items

1) Manufacturers shall at least include the following particulars on the primary container in clearly legible and indelible letters at least in Amharic or English

   a) Name of the product;
   b) Full address of the manufacturer;
   c) Name of ingredients;
   d) Optical brighteners, perfumes, enzymes, disinfectants and preservation agents irrespective of their concentration, where appropriate;
   e) Certain fragrance ingredients in concentrations exceeding 0.01 % by weight must be listed on the packaging of detergents;
   f) Form of the product;
   g) Intended use of the product;
   h) Instructions of use of the product;
   i) Precautions and warnings, where necessary; and
   j) All allergens.

2) If added, as such, at concentrations exceeding 0.01 % by weight, the allergenic fragrances for detergents intended to be used in the industrial sector, and not made available to the general public, the above mentioned requirements do not have to be fulfilled if the equivalent information is provided by means of technical data sheets, safety data sheets, or in a similar appropriate manner.

PART SIX
ADMINISTRATION MEASURE AND COMPLIANT HANDLING

32. General

1) Any importer, exporter, or wholesaler who violates requirements of this directive or other applicable laws may be subjected to appropriate administrative measure in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
2) The person against whose product or whom an administrative measure is taken in accordance with sub-article (1) of this article may lodge complaint in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
3) Complaints may be submitted by the licensee, owner of the business or a duly authorized agent of the owner or licensee. The complaint shall be submitted within 30 days from the time when administrative measure is taken.
4) Without prejudice to sub-article (1) of this article, the following may be used as illustrative lists for suspension and revocation:

33. Suspension of a license

Without prejudice to grounds of suspension provided under relevant laws, and based on the severity of the violation, the Authority shall suspend certificate of competence of the importer, exporter, or wholesaler from one month to six months, if it:

1) fails to allow inspection of its premise or products;
2) fails to submit, accurately or on time, or falsify information requested by the Authority;

3) allows a professional who is not duly licensed or who has been suspended by a competent authority from practicing his/her profession to work in the facility;
4) found holding products with the absence of authorized personnel or technical manager;
5) fails to notify the Authority of any change to professionals or premises design and/or place without approval;
6) commits other comparable violations; and
7) is suspended by other government organ (for the same duration of time).

34. Revocation of a License

Without prejudice to grounds of revocation provided under relevant laws, and based on the severity of the violation, the Authority shall revoke certificate of competence of importer, exporter, or wholesaler, up to two years, if it:

1) obtained its certificate of competence through fraudulent acts;
2) intentionally possess or sale a product in any manner from a person having no certificate of competence;
3) add or mix any substance to the product so as to increase its bulk or weight, or make it appear better or for any other similar purpose;
4) import, export or distribute a product other than the product type the certificate of competence issued for;
5) possess or sale any unregistered, adulterated, counterfeited; expired or unlabeled product;
6) continue operating its business against the terms and conditions of any suspension measures;
7) is prohibited from doing its business by another appropriate government organ;
8) impedes the work of inspectors; and
9) engage in any act which constitutes a serious violation in accordance with the directive on Administrative Measure Taking and Complaint Handling and the violation is subject to revocation measure;

35. Public and media disclosure

1) Disclosure of administrative measure shall only be allowed after 30 days of the final decision by the Authority or if the case is under complaint procedure after the final decision on the complaint.
2) Notwithstanding sub-article (1) of this article, the Authority may publicize administrative measures where failure to publicize would result public health risk.
3) Publication in accordance with sub-article (2) of this article shall be approved by the Director General of the Authority.

PART SEVEN
MISCELLANEOUS

31. Supply chain and documentations

1) An importer may only sell products to a wholesaler having valid certificate of competence from the Authority.
2) A wholesaler may only sale products to a retailer having a certificate of competence from appropriate organ.
3) The business operator shall keep the full address of the organization to whom the product is sold and the organization from whom the product is bought.
4) Documents regarding import, export or wholesale activities, including invoices, receipts, stock and bin cards, and damaged, expired, or disposed products shall be kept for one year from date of expiry of the product.
5) Periodic report regarding imported, distributed, exported, damaged, expired or disposed products shall be made to the Authority every six months.

32. Service fee

Any person who seeks regulatory service under this directive may be required to pay applicable service fee to the Authority.

33. Inapplicable laws

Any directive or customary practice which is inconsistent with this directive shall not be applicable with respect to those matters provided for in this directive.

34. Effective date

This directive shall enter into force on the date of October 11/ 2014.

Yehulu Denekew

Director General

Ethiopian Food, Medicine and Healthcare Control and administration Authority

ANNEX-I

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለልጣን

Ethiopian Food, Medicine & Health Care Administration and Control Authority

Application Form for Certificate of Competence

1. Full name of the applicant individual_____

Full address and responsibility

Region_____City_____Sub-city/Woreda_____

House No._____ Phone No._____Fax/email_____

Applicant's responsibility in the organization_____

2. Name of the organization

_____

Full address

Region_____City_____Sub-city/Woreda_____

House No._____ Phone No._____Fax/email_____

3. Full name of the owner/manager of the organization_____

Adress

Region_____City_____Sub-city/Woreda_____

House No._____ Phone No._____Fax/email_____

4. Type of business

Importer ☐ Wholesaler ☐ Exporter ☐

5. The type of product intended to hold

Ordinary cosmetic ☐ Medicated cosmetic ☐ Functional cosmetic ☐

6. Full name of technical personnel_____

Education level_____

(Attach copy of credentials: original credential must be presented during issuance of COC)

I hereby declare that the above statement is true to the best of my knowledge and belief and attached documents furnished with this application are genuine and I understand it may be used as evidence for penalty under the Ethiopian criminal law

Name of applicant individual _____ signature and date _____

For official purpose

Application Number_____

_____

Date of receipt _____

Office's Name and Signature_____

_____

ANNEX-II

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን

Ethiopian Food, Medicine & Healthcare Administration and Control Authority

Memorandum of Understanding

1. የድርጅቱ ስም_____የምርቱ ዓይነት_____
   Organization's name product type

   አድራሻ
   Address
   ክልል_____ዞን/ክ/ከተማ_____ወረዳ_____ከተማ_____ቀበሌ_____
   Region Zone/sub city Woreda City Kebele
   ስ.ቁ_____ ኢ-ሜይል_____ የአካባቢው ልዩ መጠሪያ_____
   Telephone E-mail Unique name of the place

2. የደርጅቱ ባለቤት / ተወካ ስም_____
   Name of the organization owner/Representative
3. የቴክኒካል ባለሙያ ስም_____
   Name of technical personnel

ተ.ቁ S.No	በድርጅቱ ውስጥ የተገኙ ክፍተቶች Gaps' identified	በድርጅቱ መወሰድ ያለባቸው የማስተካካያ እርምጃዎች Corrective action that has to be taken	የጊዜ ወሰን Time frame	ምርመራ Remarks

				r k

የኢንስፔክተሮች ስም ፊርማ Name of inspectors signature 1. _____ ____ 2. _____ ____ 3. _____ ____ ቀን Date _____	**የድርጅቱ ባለቤት/ ተወካይ ስምና ፊርማ** Name of the organization owner/Representative and signature _____ _____ ቀን Date _____

ማሳሰቢያ

- *ድርጅቱ የተቀመጠውን መስፈርት ከ 80% ፐርሰንት በላይ አልቶ ፍቃድ የሚሰጠው ከሆነ ጉድለቶችን ለማስተካከል ይህ የመተማመኛ ቅፅ በሶስት ኮፒ ተዘጋጅቶ 1 ኮፒ ለድርጅቱ የሚሰጥ 2ኛ ኮፒ ከድርጅቱ ፋይል ጋር ይያዛል ፣3ኛ ኮፒ ሊአንስፔክሽንና ሰረቨላንስ ዳይሬክቶሬት ለክትትል ይሰጣል።*
- *ድርጅቱ መስፈርቱን ሳያሟላ ቀርቶ በድጋሚ ፈቃድ ለማውጣት የሚመለስ ከሆነ ይህ የመተማመኛ ቅፅ በሁለት ኮፒ ተዘጋጅቶ 1ኛ ኮፒ ለድርጅቱ የሚሰጥ 2ኛ ኮፒ ከድርጅቱ ፋይል ጋር ይያያዛል።*
- *ድርጅቱ በገባው የመተማመኛ ሰነድ መሰረት ክፍተቶቹን በተቀመጠለት የጊዜ ገደብ ካላሳላ አግባብ ባለው ህግ መሰረት አስተዳዳራዊ እርምጃ ይወሰድበታል።*

NB

- *If organization comply at least 80% of the directive criteria for getting certificate of competence for taking corrective actions on deviation this memorandum of understanding form shall be prepared in three copies; 1 copy for organization, the other copy shall attached with the organization files and the third copy shall be given to inspection and surveillance directorate.*
- *If the organization does not comply with the requirements of this directive this memorandum of understanding form shall be prepared in two copies; 1 copy shall be given for the organization and the other copy shall be kept attached with the organization file.*
- *If organization does not take a corrective action within the time frame specified on the memorandum of understanding the Authority may take the administrative measure.*

ANNEX-III

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን

Ethiopian Food, Medicine & Healthcare Administration and Control Authority

Illustrative Lists of Ordinary Cosmetic

Types of Ordinary Cosmetic		
Skin	Skin care products	1. Face care products other than face mask 2. Face mask 3. Eye contour products 4. Lip care products 5. Hand care products 6. Foot care products 7. Body care products 8. Chemical exfoliation products 9. Mechanical exfoliation products 10. Other related skin care products
	Skin cleansing products	1. Toilet soap 2. Bath/shower products 3. Make-up remover products 4. External Intimate hygiene products 5. Other skin cleansing products
	Body hair removal products	1. Chemical depilatories 2. Physical depilation products 3. Other body hair removal products
	Bleach for body hair products	1. Bleach for body hair
	Correction of body odor	1. Body deodorizer
	Shaving and pre- / after-shaving products	1. Shaving products 2. Pre- / after-shaving products 3. Other shaving and pre- / after- shaving products
	Make-up products	1. Foundation 2. Concealer

products		3. face make-up products 4. Mascara 5. Eye shadow 6. Eye pencil 7. Eye liner 8. Lip stick 9. Lipstick sealer 10. Body or face paint , including "carneval make-up" 11. Other make-up products
	Perfumes	1. Hydroalcoholic perfumes 2. Non-hydroalcoholic perfumes
	Other skin products without therapeutic or functional effect	
Hair and scalp products	Hair and scalp care and cleansing products	1. Hair conditioner and shampoos 2. Scalp and hair roots care products
	Hair coloring products	1. Oxidative hair color products 2. Non-oxidative hair color products 3.Hair bleaching and dye remover products 4. Other hair coloring products
	Hair styling products	1. Products for temporary hair 2. styling permanent wave products 3. Hair relaxer / straightened products 4. Other hair styling products
	Other hair and scalp care and cleansing products	1. Hair sun protection products 2. Other hair and scalp products 3. Nail
Nail and cuticle products	Nail varnish and remover products	1. Nail varnish / Nail make-up 2. Nail varnish remover 3. Nail varnish thinner 4. Nail bleach 5.Other nail varnish and remover products
	Nail care / nail hardener products	1. Nail care products 2. Nail hardener 3. Other nail care / nail hardener products
	Nail glue remover products	Nail glue remover
	Other nail and cuticle products	1. Cuticle remover / softener 2. Nail sculpting products 3. Other nail and cuticle products

Oral hygiene products (subject to Article 7 (1) of this directive)	Tooth care products	1. Toothpaste 2. Tooth cleansing powder / salt 3. Other tooth care products
	Mouth wash / breath spray	1. Mouth wash 2. Breath spray
	Tooth whiteners	1. Tooth whiteners
	Other oral hygiene products	Other oral hygiene products

ANNEX-IV

Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Application for Registration

1. Name of applicant organization _____
   Full address

   Region_____City_____Sub-city/Woreda_____

   House No._____ Phone No._____Fax/email_____

2. Name of the individual _____
   Full address and responsibility

   Region_____City_____Sub-city/Woreda_____

   House No._____ Phone No._____Fax/email_____

   Applicant's responsibility in the organization_____

3. Name of the product to be registered _____
4. Type of the product _____
5. Color of the product _____
6. Presentation (Pack size, content) _____
7. Shelf life (in months) _____

8. Name of the ingredients, strength (%) and function

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

_____ _____ _____

_____ _____ _____

9. Main indication _____
_____
_____
_____

10. Manufacturer information

Name of the manufacturer_____

Full address _____

Plant address_____

Postal address _____

Phone number_____

Fax number_____

E-mail_____

Website_____

11. List or annotate required documents or materials (attached with this form)

_____

_____

_____

_____

I HEREBY DECLARE THAT THE ABOVE STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF AND ATTACHED DOCUMENTS FURNISHED WITH THIS APPLICATION ARE GENUINE AND I UNDERSTAND IT MAY BE USED AS EVIDENCE FOR PENALTY UNDER THE ETHIOPIAN CRIMINAL LAW

Name of applicant individual signature and date

_____ _____

For official purpose

Application Number_____

Date of receipt _____

Registration Number_____

Registration Date_____

Office's Name and Signature_____

Date_____

ANNEX V

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን

Ethiopian Food, Medicine & Healthcare Administration and Control Authority

LIST OF PROHIBITED INGRIDIENTS

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, *e.g.* ambenomium chloride
7.	α-Piperidin-2-yl benzyl acetate laevorotatory threoform (Levophacetoperane) and its salts
8.	α-Santonin ((3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphto (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 (amydricaine, 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.	11α-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)ethyldimethylamine maleate
23.	2-α-Cyclohexylbenz,yl (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-IS0)
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-tetrahydronaphtalen
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 dihypoiodite
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 *Aconitum napellus L.*) and its salts
70.	*Aconitum napellus L.* (leaves, roots and galenical preparations)
71.	*Adonis vernalis 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.	*Ammi majus* and its galenical preparations
79.	Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))
80.	Amyl nitrites
81.	*Anamirta cocculus 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.	*Apocynum cannabinum 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; *Aristolochia spp.* and their preparations
91.	Arsenic and its compounds
92.	*Atropa belladonna 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.	Benzilonium 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.	Butanilicaine and its salts
118.	Butopiprine and its salts
119.	Cadmium and its compounds
120.	*Calviceps purpurea Tul.*, its alkaloids and galenical preparations
121.	Cantharides, *Cantharis vesicatoria*
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.	*Chenopodium ambrosioides* (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, *e.g.* 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.	*Colchicum autumnale L.* 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.	*Conium maculatum L.* (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.	*Datura stramonium L.* and its galenical preparations
177.	Deanol aceglumate
178.	Decamethylenebis (trimethylammonium) salts, *e.g.* 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.	Difencloxazine
188.	Digitaline and all heterosides of *Digitalis purpurea L.*
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.	Fenyramidol
217.	Fluanisone
218.	Fluoresone
219.	Fluorouracil
220.	Furazolidone
221.	Furfuryltrimethylammonium salts, *e.g.* furtrethonium iodide*
222.	Furocoumarines (*e.g.* 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, *e.g.* 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.	*Hyoscyamus niger L.* (leaves, seeds, powder and galenical prepations)
247.	Inorganic nitrites, with the exception of sodium nitrite
248.	Inproquone
249.	Iodine
250.	Ipecacuanha (*Cephaelis ipecacuanha Brot.* And related species) (roots, powder and galenical preparations)
251.	Isocarboxazide
252.	Isometheptene and its salts
253.	Isoprenaline
254.	Isosorbide dinitrate
255.	*Juniperus sabina L.* (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.	*Lobelia inflata L.* and its galenical preparations
260.	Lobeline and its salts
261.	Lysergide and its salts
262.	Malononitrile
263.	Mannomustine and its salts
264.	Mecamylamine
265.	Mefeclorazine 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, *e.g.* 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(ethyldimethylammonium) salts, *e.g.* azamethonium bromide
286.	N,N'-Pentamethylenebis (trimethylammonium) salts, *e.g.* 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 (*e.g.* 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 *Laurus nobilis L.*
310.	Oleandrin
311.	o-Phenylenediamine and its salts
312.	Oxanamide 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.	*Physostigma venenosum Balf.*
330.	*Phytolacca Spp.* and their preparations
331.	Picric acid
332.	Picrotoxin
333.	Pilocarpine and its salts

S/N	Substance
334.	*Pilocarpus jaborandi 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.	*Prunus laurocerasus L.* ('cherry laurel water')
347.	Psilocybine
348.	*Pyrethrum album L.* and its galenical perparations
349.	Pyrithione sodium (INNM)
350.	Pyrogallol
351.	Radioactive substances (1)
352.	*Rauwolfia serpentina* alkaloids and their salts
353.	Safrole except for normal content in the natural essences used and provided the concentration does not exceed: ▪ 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.	*Schoenoocaulon officinale 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.	*Solanum nigrum L.* and its galenical preparations
360.	Sparteine and its salts
361.	Spironolactone
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.	*Strophantus* species and their galenical preparations
368.	Strychnine and its salts
369.	*Strychnos* 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.	(a) The skull, including the brain and eyes, tonsil and spinal cord of: - 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; (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: - 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.	*Thevetia neriifolia 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.	Tranylcypromine 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.	*Urginea scilla Stern.* and its galenical perparations
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 perparations
417.	*Veratrum Spp.* 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

ANNEX VI

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Ethiopian Food, Medicine & Healthcare Administration and Control Authority

List of substances not allowed in cosmetic 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	(a) Talc	(a) 5% (by mass/mass as boric acid)	(a) 1. Not to be used in products for children under 3 years of age 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)	(a) 1. Not to be used for children under 3 years of age 2. Not to be used on peeling or irritated skin
		(b) Products for oral hygiene	(b) 0.1% (by mass/mass as boric acid)	(b) 1. Not to be used in products for children under 3 years of age	(b) 1. Not to be swallowed 2. Not to be used for children under 3 years of age
		(c) Other products (excluding bath products and hair waving products)	(c) 3% (by mass/mass as boric acid)	(c) 1. Not to be used in products for children under 3 years of age 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)	(c) 1. Not to be used for children under 3 years of age 2. Not to be used on peeling or irritated skin

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	(a) 18% (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) Hair waving products	(b) 8% (by mass/mass as boric acid)		(b) Rinse well
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products: - General use	- 8% ready for use pH 7-9.5	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.
		- Professional use	- 11% ready for use pH 7-9.5		
		(b) Depilatories	- 5% ready for use pH 7-12.7		
		(c) Other hair care products which are removed after application	- 2% ready for use pH 7-9.5 Percentages calculated as thioglycollic acid.		

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	Hair waving or straightening products: - General use - Professional use	- 8% ready for use pH 6-9.5 - 11% ready for use pH 6-9.5 Percentages calculated as thioglycollic acid.	The directions for use 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 off with plenty of water and seek medical advice. ▪ Wear suitable gloves.	- 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_2O_2 (40 volumes) present or released 4% of H_2O_2 present of released 2% of H_2O_2 present or released 0.1% of H_2O_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 vontact 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 warni which must be printed on t 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 applica - Do not use to dye eyelashes eyebrows - Rinse eyes immediately if product comes into contact them 2. - For professional use only - Contains resorcinol - Rinse eyes immediately if product comes into contact 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 child - Avoid contact with eyes (b) - Keep out of reach of chidr - Avoid contact with the eye

Reference number	Substance	RESTRICTIONS			Conditions of use and warni which must be printed on t 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 monofluorophosophate
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 warni which must be printed on t 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 fluorid
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 ammoni 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) propy (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 warni which must be printed on t 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-ammoniu fluoride
40	Sodium fluorosilicate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains sodium fluorosilica
41	Potassium fluorosilicate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Schedule		- Contains potassium fluorosil
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) imidazolidir 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 warni which must be printed on t 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 product comes into contact them
49	Selenium disulphide	Anti-dandruff shampoo	1%		- Contains selenium disulphi - Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxide complexes AlxZr (OHjyClz and the aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	▪ 20% as anhydrous aluminium zirconium chloride hydroxide ▪ 5.4% as zirconium	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	▪ Stabilizer for hydrogen peroxide in rinse-off hair care preparations. ▪ Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations.	▪ 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 warni which must be printed on t 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		- Keep away from children. - Avoid all contact with the e - 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%		- Contains magnesium fluoric

Reference number	Substance	RESTRICTIONS			Conditions of use and warni which must be printed on t 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
57	Strontium chloride hexahydrate	(a) Toothpaste (b) Shampoo and face care products	(a) 3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.5% (b) 2.1% calculated as strontium. When mixed with other permitted strontium compounds, the total strontium content must not exceed 2.1%		- Contains strontium chlorid - Frequent use by children is advisable
58	Strontium acetate hemihydrate	Toothpaste	3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.5%		- Contains strontium chlorid - Frequent use by children is advisable
59	Talc: Hydrated magnesium silicate	a) Powdery products intended to be used by children b) Other products			a) – Keep powder away from children's nose and mouth

Reference number	Substance	RESTRICTIONS			Conditions of use and warni which must be printed on t 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%	- 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%	- 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 warni which must be printed on t 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-nitroso-dialkanolamine 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 childre - 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 produts must meet the hydrogen peroxide release requirements	- Avoid contact with eyes - Rinse eyes immediately if product comes into contact 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 sacchrinate 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-VII

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን

Ethiopian Food, Medicine & Healthcare Administration and Control Authority

List of dyes, pigments and color additives

Table 1: dyes suitable for use in all cosmetic 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 cosmetic 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**
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	Dibromodiiodofluorescein	-
45456	Orange	Solvent Orange 17	Orange TR	-

(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	-	-

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 (*Curcuma longa*)	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-VIII

የኢትዮጵያ የምግብ፣የመድኃኒትና የጤና ክብካቤ አስተዳደርና ቁጥጥር ባለስልጣን

Ethiopian Food, Medicine & Healthcare Administration and Control Authority

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 labeling 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'-Tetra-chloroazoxybenzene 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%		

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
	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%		

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
	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 Prohibted in products for children under three years of age, in oral hygiene products	

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
			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%	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-IX

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Ethiopian Food, Medicine & Healthcare Administration and Control Authority

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 percent	-
2.	*N,N,N*-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 percent	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 percent (expressed as acid)	-
6.	3,3`(1,4-	10 percent	-

	Phenylenedimethylene)-bis (7,7-dimethyl-2-oxo-bicyclo[2.2.1]hept-1-ylmethanesulphonic acid) [Terephthalylidene dicamphor sulfonic acid] and its salts	(expressed as acid)	
7.	1-(4-*tert*-Butylphenyl)-3-(4-methoxyphenyl) propane-1,3-dione (Avobenzone(INN))[Butyl methoxy dibenzoylmethane]	5 percent	-
8.	*a*-(2-Oxoborn-3-ylidene) toluene –4-sulphonic acid [Benzylidene camphor sulfonic acid] and its salts	6 percent (expressed as acid)	-
9.	2-Ethylhexyl2-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-meethoxycinnamate [Isoamyl *p* – methoxycinnamate]	10 percent	-
14.	Tris (2-ethylhexyl) 4,4′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-*tert*-butylcarbamoylanilino)-1,3,5-triazine-2,4-diyldiimino]dibenzoate	10 percent	-
17.	3-(4-Methlbenzylidene) 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 (INNM))	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*H*-benzimidazole-4,6-disulfonate)	10 percent (expressed as acid)	-
24.	5,5′-Bis (2-ethylhexyloxy)-2,2′-(6-*p*-methoxyphenyl-1,3,5-triazine-2,4-diyl)diphenol	10 percent	-
25.	a-(Trimethylsilyl)-w-(trimethylsilyloxy)poly-[dimethyl)silylene]-co-[oxy(methyl)(2-[p-[2,2-bis(ethoxycarbonyl)-vinyl]-phenoxy]- 1-methylene ethyl) silylene-co-[oxy(methyl)(2-[p-[2,2-bis(ethoxycarbonyl)vinyl)]-phenoxy]prop-1-enyl)silylene]where there are usually 60 polymeric units, of which the first part of the copolymer provides 56 (Dimethicodiethyl/Benzalmaionate)	10 percent	-
26.	Titanium dioxide	25 percent	-

ANNEX-X

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Ethiopian Food, Medicine & Healthcare Administration and Control Authority

Allergenic Fragrances Ingredients

These ingredients appear on the list of substances in Annex III, Part 1 of Directive 76/768/EEC (INCI names in brackets).

- Amyl cinnamal (AMYL CINNAMAL) o Benzyl alcohol (BENZYL ALCOHOL)
- Cinnamyl alcohol (CINNAMYL ALCOHOL)
- Citral (CITRAL)
- Eugenol (EUGENOL)
- Hydroxycitronellal (HYDROXYCITRONELLAL)
- Isoeugenol (ISOEUGENOL)
- Amylcinnamyl alcohol (AMYLCINNAMYL ALCOHOL)
- Benzyl salicylate (BENZYL SALICYLATE)
- Cinnamal (CINNAMAL) o Coumarin (COUMARIN)
- Geraniol (GERANIOL)
- 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexenecarboxaldehyde (HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE)
- Anisyl alcohol (ANISE ALCOHOL)
- Benzyl cinnamat (BENZYL CINNAMATE)
- Farnesol (FARNESOL)
- 2-(4-tert-Butylbenzyl)-propionaldehyde (BUTYLPHENYL METHYLPROPIONAL)
- Linalool (LINALOOL)
- Benzyl benzoate (BENZYL BENZOATE)
- Citronellol (CITRONELLOL)
- Hexyl cinnam-aldehyde (HEXYL CINNAMAL)
- D-Limonene (LIMONENE)
- Methyl heptin carbonate (METHYL 2-OCTYNOATE)
- 3 -Methyl-4-(2,6,6-trimethyl-2-cyclohexen- 1 -yl)-3 -buten-2-one (ALPHA-ISOMETHYL IONONE) o Oak moss extract (EVERNIA PRUNASTRI EXTRACT)
- Treemoss extract (EVERNIA FURFURACEA EXTRACT)