

# NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

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#### **Commencement:**

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honorable Minister of Health hereby makes the following Regulations:-

## Scope

All cosmetics manufactured, imported, exported, advertised, sold, distributed or used in Nigeria shall be registered in accordance with the provisions of these Regulations.

## 2. Prohibition

No person shall manufacture, import, export, distribute, advertise, display for sale, offer for sale, sell, or use a cosmetic, unless a label has been affixed thereto with the information required by these Regulations appearing on both the inner and outer container (as applicable).

## 3. Labeling information

- (1) All information required to be indicated on the label shall be informative, accurate, prominent, legible and distinct.
- (2) All statements shall appear in font size and style type which is adequate for clarity and on sufficient contrasting background without obscuring designs or vignettes or crowding within written, printed or graphic matter.
- (3) The letters of the name of the cosmetic product and the net content shall be of a size reasonably related to the predominant character on the label.
- (4) Labelling shall not be false, misleading, deceptive or likely to create an erroneous impression regarding its character, quality, quantity and origin;
- (5) The label space shall not be used to present information, statement or graphics not required by these Regulations in such a manner that will make the label space insufficient for the prominent placing of such information or statements required under these Regulations.
- (6) All cosmetic products labels shall state the following;
  - (a) the brand name (where applicable),
  - (b) the product statement of identity,
  - (c) lot or batch number,
  - (d) net content,
  - (e) expiry date,
  - (f) manufacturer's name and country of origin,
  - (g) registration number assigned to it in a manner as prescribed by the Agency

- (h) storage conditions; and any other information as may be prescribed by the Agency.
- (7) Where a cosmetic container is covered by a wrapper, the label shall be readily legible through the outer wrapper and shall not be obscured by it.
- (8) Where the wrapper carries the required information, it shall be affixed in a manner that is not removable from the cosmetic container.
- (9) No label shall bear words, pictorial or other means which refers to any other product or falsely suggests either directly or indirectly, that the cosmetic product is connected with such other product.
- (10) All information and statements as required by these Regulations shall appear on the part or panel of the label which is presented or displayed under customary conditions of purchase.
- (11) Any claims on the cosmetic product shall be substantiated.
- (12) All information for a cosmetic product shall be in English Language, and may include any other languages.

## 4. Product identity

- (1) The outer and inner labels of a cosmetic shall be required to bear the name of the cosmetic product which shall indicate the accurate nature of the cosmetic.
- (2) Where a common name/statement of identity has been established for the cosmetic, it shall be used in conjunction with the brand name of the cosmetic product.
- (3) Where no common name/statement of identity exists for a cosmetic product, an appropriate descriptive name shall be affixed thereto.
- (4) Where a coined or fanciful name is used for the cosmetic product, the name shall not be misleading and shall be accompanied by an appropriate descriptive term.

## 5. List of ingredients

- (1) A complete list of ingredients used in preparing the cosmetic product shall be declared on the outer label and inner label where appropriate in decreasing order of predominance.
  - (a) fragrance, colour or flavour may be listed in any order after the other ingredients as fragrance, colour or flavour.
  - (b) an ingredient that is a fragrance, colour and flavour shall be each be designated by internationally identified name or code.
- (2) Where there is no outer packaging, the list of ingredients shall appear on the inner label.
- (3) Ingredients in concentrations of less than 1% may be listed in any order after those concentrations of 1% or more.
- (4) For decorative cosmetics, marketed in several colour shades, all colouring agents may be listed, preceded by the words "may contain".
- (5) Where the ingredients of a cosmetic product have more than one component the name of the components shall be included in the list of ingredients.
- (6) The declaration of ingredients shall be prominent, readable and understood by ordinary individuals under normal conditions of purchase.
- (7) Where a grade designation is used, it shall be appropriately stated in a manner that is not misleading or deceptive.

- (8) Where a cosmetic product contains a pharmaceutically active ingredient, the declaration of ingredients shall declare the active drug ingredients in accordance with the Agency's Drug Labeling Regulations 2019.
- (9) Where the ingredients of a cosmetic product is known to cause hypersensitivity, such shall be declared on the label.
- (10) Where multi-packs are involved the following shall apply;
  - (a) where the ingredient labeling is on the outer packaging, the ingredients for each product may be separately listed or combined into one list;
  - (b) where labeling on the outer packaging is impossible for practical reasons or impracticable for reasons of size or shape, the list shall be given on a leaflet, label, tag, tape or card enclosed with the product and the consumer shall be referred to the text either by abbreviated information or by a special symbol on the outer pack;
  - (c) if the products within the multi-pack have containers which are individually labeled or printed with an ingredient list, there is no need for a separate leaflet, label, tape, tag or card; and
  - (d) in the case of transparent packaging, where the ingredient labeling of the products is clearly visible, separate labeling is not required.
- (11) For the purposes of labeling, the following shall not be regarded as cosmetic ingredient and need not be shown on the label:
  - (a) impurities of the raw materials;
  - (b) subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product; and
  - (c) materials used in strictly necessary quantities as solvents or as carriers for perfumes and aromatic compositions.

## 6. Net content of cosmetic product

- (1) The accurate average net content of every cosmetic product shall be declared on the inner and outer label in the metric system.
- (2) Products that have only an inner label shall meet the same requirements as those for the outer labels of products having both an outer and inner label.
- (3) The declaration of the average net content of the cosmetic product shall be required to be made in the case of:
  - (a) liquid cosmetic in volume;
  - (b) solid cosmetic by weight and number or count (where applicable); and
  - (c) Semi-solid or viscous cosmetic by weight or volume.
- (4) The declaration shall accurately reveal the quantity of cosmetic in a package exclusive of wrappers and other material packed therewith, provided that:
  - (a) in the case of cosmetics packed in containers designed to deliver the cosmetic under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed and the propellant is included in the net quantity declaration;
  - (b) in the case of a package which contains the integral components making up a complete kit, and which is designed to deliver the components in the manner of an application, the

- declaration may state the net quantity of the contents in non-deceptive terms of the number of applications available in the kit when the instructions for use as shown on the container are followed; and
- (c) the declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of Good Distribution Practice or by unavoidable deviations in Good Manufacturing Practice will be recognized along with variations from stated quantity of contents which shall not be unreasonably large.

# 7. Name, address and country of manufacture to be declared

- (1) The name and full location address of the manufacturer and packer of a cosmetic product shall be specified on both the inner and outer label (where present) in such a manner that is easily readable.
- (2) Where the name of the Certificate of Registration Holder of a cosmetic product is specified on the inner and outer label, it shall be easily readable.
- (3) When a cosmetic product undergoes any processing which affects its contents in another country, such a country shall be considered as the country of manufacture for the purpose of labeling.
- (4) Notwithstanding the provisions of Regulations 7 (1) a cosmetic packed in a container of that is 10 cm (or equivalents) or less shall indicate the following:-
  - (1) the brand name (where applicable),
  - (a) the product statement of identity,
  - (b) lot or batch number,
  - (c) net content,
  - (d) expiry date,
  - (e) manufacturer's name and full location address,
  - (f) registration number assigned to it in a manner prescribed by the Agency.

#### 8. Batch number

The batch number shall be indicated on both the inner and outer labels (where present) of all cosmetic products and where it is impossible, for reasons of size, for details of the batch number to appear on both the inner and outer packaging, the details shall be given on the inner packaging.

#### 9. Date marking instructions

- (1) The date marking shall be stated for all cosmetic products and shall be stated on both the inner and outer labels (where present).
- (2) The batch number and date markings shall not be pre-printed on the label.

## 10. Storage condition

The required storage conditions shall be specified on both the inner and outer labels (where present).

## 11. Brand name/Trade mark

- (1) The brand name or trade mark shall be displayed on the label and shall not give a wrong impression of the nature, quality or substance of the cosmetic product.
- (2) Where the brand name or trade mark registration is in conflict with any Regulations or requirements of the Agency, the latter shall supercede and prevail.

## 12. Registration number

All cosmetic products shall bear on its label its NAFDAC Registration Number (NAFDAC Reg. No.) issued on the Certificate of Registration in such a manner as prescribed by the Agency.

#### 13. Directions for use

Directions for use, including reconstitution, where applicable, shall be included on the label to ensure correct utilization of the cosmetic product.

## 14. Warnings and cautions

- (1) The outer and inner label of every cosmetic product shall carry clear and adequate warning to prevent any danger in the use of the product.
- (2) Specific requirements shall apply to the classes of cosmetics products mentioned in Schedule A to these Regulations.

## 15. **Soap**

- (1) Where soap is supplied in a container or wrapper, it shall comply with the labeling requirements set forth in these Regulations.
- (2) Where soap is not supplied in a container or wrapper, the name and address of the manufacturer or Certificate of Registration Holder and the batch number shall be given on either:
  - (a) the soap itself; or
  - (b) the packaging in which it is exposed for supply; or
  - (c) The container in which it was packed before being exposed for supply.
  - (d) the manufacturing and expiry dates
- (3) The following shall be provided on a leaflet supplied with the soap;
  - (a) warning statements and precautionary information;
  - (b) product function (where applicable); and
  - (c) ingredient listing

## 16. Displayed information not in conflict with mandatory requirement.

- (1) Any information displayed on a label which misleads or deceives a consumer in anyway shall constitute an offence under these Regulations.
- (2) No person shall remove, add to, alter, deface or render illegible any statement upon a label printed on or attached to a wrapper or container in pursuance of these Regulations.

## 17. Penalty.

- (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of:
  - (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and
  - (b) a body corporate, to a fine not exceeding N100, 000.
- (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-
  - (a) director, manager, secretary or other similar officer of the body corporate; or
  - (b) partner or officer of the firm or
  - (c) trustee of the body concerned ;or
  - (d) person concerned in the management of the affairs of the association ;or
  - (e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

## 18. Forfeiture after conviction

- (1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-
  - (a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;
  - (b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.
- (2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

## 19. Interpretation

In these Regulations, unless the context otherwise requires:—

"Address" means where the business of manufacture or sale or distribution or storage or display of cosmetic product is carried out which includes the house number, plot number, street name, Town/City, State, Country, etc.

"Agency" means The National Agency for Food and Drug Administration and Control;

"Foaming Detergent Bath Products" means a foaming detergent bath product--also known as bubble bath product--is, for the purpose of this Regulation, defined as "any product intended to be added to a bath for the purpose of producing foam that contains a surface-active agent serving as a detergent or foaming ingredient."

"Container" means any form of packaging of cosmetics for sale as a single item whether by completely or partially enclosing the cosmetics and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

"Decorative cosmetics" means cosmetic products intended to modify the appearance of the area to which they are applied, usually by the use of colour.

"Ingredient" includes all substances or mixture of substances used in the manufacture or preparation of cosmetic;

"Label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a package (container) of a cosmetic product.

"Inner label" means primary packaging material label;

"Outer label" Outer label" means secondary packaging material label;

"Package labelling" includes the label on the immediate container plus all other printed matter such as outer wrapper, carton or leaflet associated with the package;

"Principal display panel (PDP)" means the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for display for retail sale;

"Lot or Batch number" means the number or a combination of numbers and letters specifically given to a cosmetics product which is linked to the manufacturing history of the product;

A label may consist of more than one panel. It may consist of a front panel, side panels and a back panel. Back and side panels are generally called information panels.

The information below shall appear on the label of the outer container which usually is a box. The immediate container holding the cosmetic product also is the outer container if it is not displayed in a box.

# Outer Container (Or Label of Single Container Product)

Principal Display Panel	Information Panels
Name of product	Directions for safe use
	Warnings
Identity	Name and Address of the Manufacturer
	Ingredient List
Net quantity of contents	Any other required information

The information below shall appear on the label of the inner (immediate) container holding the cosmetic product.

# Inner Container (If Packaged in an Outer Container)

Front Panel	Information Panels
Name of Product	Directions for safe use
	Warnings
	Name and Address of the Manufacturer
	Ingredient List
	Net quantity of contents
	Any other required information

# 20. Repeal

- (1) These Regulations repeals the provisions of Cosmetics Product Labelling Regulations 2005.
- (2) The repeal of these Regulations specified in Regulations 22(1) shall not affect anything done or purported to be done under the repealed Regulations

# 21. Citation

These Regulation may be cited as the Cosmetics Product Labelling Regulations,.

#### **SCHEDULE A**

(1) Hair Dyes: Hair dyes containing para-phenylenediamines or other coal tar dye intermediates, shall bear the following on its outer and inner labels:

"CAUTION": This product contains ingredients that may cause skin irritation on certain individuals and preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eye lashes or eyebrows as to do so may lead to blindness".

Directions for preliminary sensitivity test shall be indicated on the product.

- (2) Products for Genital use: A product for use in the genital area shall carry all Directions and Warnings as required for the safe use of the product.
- (3) Pressurized Metal Containers: If the packaging of a pressurized metal Container has only an inner label, the following items shall be provided:-
  - (a) the explosive symbol shall appear on the display panel of the label,
  - (b) the word "CAUTION" shall appear on the display panel of the label and this signal word shall appear immediately below the symbol and shall be printed in boldface type,
  - (c) the message "CONTAINER MAY EXPLODE IF HEATED" shall appear on the display panel of the label and this statement shall appear immediately below the signal word in boldface type,
  - (d) the following statement shall appear on any part on the Panel of the label, except the bottom of the container:

"Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat and do not puncture or incinerate container or store at temperatures over 50 degrees Celsius".

(4) Warning--Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate.

The words "Avoid spraying in eyes" may be omitted if the product is not expelled as a spray. Example: Aerosol shave cream.

The word "puncture" may be replaced by the word "break" if the product is packaged in a glass container.

If the product is intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence of the warning.

- (5) For pressurized metal containers having both an outer and inner label, the following shall apply; if the net quantity of product is:
  - (a) more than 120ml/120g, the outer and inner label shall comply with the requirements of Regulation 15(2)(c) i-iv,
  - (b) 120ml/120g or less but more than 60ml/60g, the outer label shall comply with the requirements of Regulation 15 (2)(c). i-iv and the inner label shall comply with paragraph 15(2)(c) i-iii but may also comply with paragraph 15(2)(c) iv,
  - (c) 60ml/60g or less, the outer label shall comply with paragraph 15(2)(c) i-iv and the inner label shall comply with paragraph 15(2)(c) i and ii but may also comply with paragraph 15(2)(c) iii & iv.
  - (d) Where the information specified in this Regulation 15 is impracticable for reasons of size or shape, the information shall be given on a label, tag, tape or card attached to the product and the consumer shall be referred to it, either by abbreviated information or a special symbol on both the inner container and outer packing.

## (6) Foaming Detergent Bath Products:

The caution stated below is required on the label of any foaming detergent bath product:

Caution - Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

If the bubble bath product is intended for use by children, the phrase "Keep out of reach of children" may be expanded to further read "except under adult supervision."

The Regulation further requires that the label shall bear adequate directions for safe use of the product.

MADE at Abuja thisday of	2019	9
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Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)