

ANVISA DIRECTIVE- RDC No. 7, 10 FEBRUARY 2015 (COSMETICS & TOILETRIES AND PERFUMES REGISTRATION PROCEDURES AND REQUIREMENTS)

The technical requirements are regulated for the regularization of toiletries, cosmetics and perfumes and provides other provisions.

The Board of the National Health Surveillance Agency, in the use of powers conferred on it by sections III and IV of art. 15 of Law No. 9,782, of January 26 1999, item V, and §§ 1 and 3 of art. 5 of the Bylaws (Internal Regulations) approved under Annex I of Ordinance No. 650 of ANVISA, of 29 May 2014, in view of the provisions of items III of art. 2, III and IV of art. 7 of Law No. 9782, 1999 in art. 35 of Decree No.3029 of April 16, 2009, and the Improvement Agency's Regulatory Process Improvement Program established by Ordinance No. 422 of April 16, 2008, at the meeting held on October 9, 2014, adopts the following Resolution of the Board of Director, and I the Director-President determine its publication:

Art. 1. It is approved the Technical Regulation on the definition, classification, technical requirements, the labeling and electronic procedure for regularization of personal hygiene products (toiletries, personal hygiene products) cosmetics, and perfumes under this Resolution.

Art. 2. This Regulation incorporates into national law the GMC MERCOSUR resolutions no. 110/94 "Definitions of Cosmetic Products"; 07/05 "Toiletries, Cosmetics, and Perfumes, Classification"; 26/04 " Specific Toiletries, Cosmetics, and Perfumes, Technical Requirements"; 36/04 "Toiletries, Cosmetics, and Perfumes General Mandatory Labeling"; 36/99 "Specific Labeling for Toiletries, Cosmetics, and Perfumes"; and 24/95 "Requirements for Mercosur and Extra-Zone Cosmetic Registration-and Licensing of Representative Registry Holder Companies in the Receiver Party Importers ".

CHAPTER I INITIAL PROVISIONS

section I objective †

Art. 3. This Regulation aims to update the necessary procedures for the regularization of toiletries, cosmetics, and perfumes through simplification of procedures aimed at improving the quality of information and speed of analysis.

section II scope

Art. 4 This regulation applies to toiletries, cosmetics, and perfumes classified as Grade 1 and Grade 2 according to the definitions in Annex I and II of this Resolution

Art. 5 The specific technical requirements are established for personal hygiene products, cosmetics and perfumes, according to Annex III of this Resolution.

Art. 6 The additional requirements are established for toiletries, cosmetics, and perfumes imported into Mercosur and extra-zone according to Annex IV of this Resolution. Art. 7 The requirements for the general mandatory labeling are for s personal hygiene products, cosmetics, and perfumes, according to Annex V of this Resolution.

Art. 8 The specific labeling requirements are established for personal hygiene products, cosmetics, and perfumes, according to Annex VI of this Resolution.

Art. 9. Environment Odorizing Products are classified as Grade 1 personal hygiene products, cosmetics, and perfumes.

Art. 10. The product regularization holder must possess supporting data attesting to the quality, safety and efficacy of its products and the suitability of their wordings on the label, and the technical requirements according to Annex III of this Resolution, which shall be submitted to the health authorities, when requested or during inspections. It should also ensure that the product poses no health risk when used in accordance with the instructions for use and other measures contained in the product's sales package during its period of validity.

Single paragraph. The company must attach to the transaction (during the online regularization) the Responsibility Disclaimer, duly signed by the Technical Responsible manager and the company Legal representative, according to Annex VII.

Art. 11. The personal hygiene products, cosmetics, and perfumes should meet the following provisions:

I- List of preservative action substances allowed for toiletries, cosmetics, and perfumes - Resolution - RDC No. 29 of June 10, 2012 and its updates;

II- List of permitted colorants for toiletries, cosmetics, and perfumes - Resolution - RDC No. 44 of August 9, 2012 and its updates;

III- List of substances that personal hygiene products, cosmetics, and perfumes should not contain except in the conditions and restrictions set for Resolution – RDC No. 03 of January 18, 2012 and its updates;

IV- List of ultraviolet filters allowed to toiletries, cosmetics, and perfumes - Resolution - RDC No. 47 of March 16, 2006 and its updates;

V- List of substances that cannot be used in personal hygiene products, cosmetics and perfumes - Resolution - RDC No. 48 of March 16, 2006 and its updates.

Art. 12. The personal care products, cosmetics, and perfumes, classified as Grade 1, must comply with the current regulations and also the following criteria:

I- Do not contain substances of the Restrictive List, contained in Resolution - RDC No. 03 of 18 January 2012, and its updates, that are specific to products classified as Grade 2, except for the cases in which the presence of the substance in the formulation does not alter the purpose of the product and do not decharacterizes classification as Grade 1;

II- Do not contain substances of the Ultraviolet Filter to protect the skin against damaging effects of sunlight, contained in Resolution - RDC No. 47 of 16 March 2006 and its updates, as the presence of these substances characterizes Grade 2 product;

Art. 13. There shall be not permitted the packaging in the form of aerosols for talc powders.

Art. 14. The containers of the products presented in the form of aerosol, with glass wrapped in plastic material, must contain small holes to output the content, in case of glass break.

Art. 15. The containers of product in the form of pressed aerosols shall not have the capacity exceeding five hundred (500) milliliters.

Art. 16. The provisions of this resolution does not preclude compliance with other regulations provided for in the health legislation, relevant to personal hygiene products, cosmetic, and perfumes.

Art. 17. The labeling of personal care products, cosmetics, and perfumes should not contain mentions and therapeutic indications, nor designations and indications that lead to error, deception or confusion as to its provenance, origin, composition, purpose or safety.

Art. 18. The labeling of Grade 1 and Grade 2 personal care products, cosmetics, perfumes, must contain the number of the company's License Authorization– AFE - and the number of the process generated at Anvisa's regularization system on the label, that will correspond to the registration number.

§ 1. For products Grade 1 and Grade 2, exempt from registration, the sale may occur only after their appearance at the Anvisa's portal registration database.

§ 2. For products Grade 2 subject to registration, the sale may only occur after the published registration in the Federal Official Gazette.

CHAPTER II OTHER MANDATORY LABELLING

Art. 19. In addition to the warnings set forth in Annex VI of this Resolution, it shall be printed additionally, on a mandatory basis, at the primary and secondary packaging, the specific highlighted words below:

I- AEROSOLS: "Evite inalação deste produto" (Mandatory statement open translated as –"Avoid inhalation of this product.")

II NEUTRALIZING, PRODUCTS FOR CURLING AND SMOOTHING THE HAIR: "Este preparado somente deve ser usado para o fim a que se destina, sendo PERIGOSO para qualquer outro uso" ("This product should only be used for the purpose it is intended, and is DANGEROUS to any other use.")

III- HAIR LIGHTENER AGENTS AND HAIR DYES: the labels of dyes and bleaching hair agent's that contain substances capable of producing acute or chronic intoxications should contain the warnings: "CUIDADO. Contém substâncias passíveis de causar irritação na pele de determinadas pessoas. Antes de usar, faça a prova de toque" ("CAUTION. It contains substances that may cause skin irritation in some people. Before use, perform the proof of touch.")

IV- BRONZING SIMULATORS: The labels of products intended to simulate skin tanning should contain a warning: "Atenção: não protege contra a ação solar" ("Attention: does not protect against solar action").

CHAPTER III PROCEDURES FOR REGULARIZATION

section I Electronic Automation System (Online Regularization System)

Art. 20. It is established the electronic procedure for regularization of toiletries, cosmetics, and perfumes, Grade 1 and Grade 2, at Anvisa.

§1. The health regularizations (registration or exemption from registration) for toiletries, cosmetics, and perfumes, are now held on an electronic procedure, through the Anvisa's portal.

§2 The advertising of regularization of toiletries, cosmetics, and perfumes Grade 1 and Grade 2 that are exempt from registration is ensured by its presentation at the Anvisa's portal (public cosmetics electronic database).

§3 The advertising of regularization of toiletries, cosmetics and perfumes Grade 2 subject to registration is ensured by its publication in the Federal Official Gazette (through Anvisa's ordinances).

§4 The necessary guidelines to the electronic procedure for the regularizations s toiletries, cosmetics, and perfumes are available at the Anvisa's electronic portal

Art. 21. The documents generated at the end of the electronic procedure should be kept at the company.

Single paragraph. The Responsibility Disclaimer must be signed by the Technical Director Manager and the company's Legal Representative, complementing all the documentation of the product (transmitted online to Anvisa's electronic regularization system).

Art. 22. The regularization of toiletries, cosmetics, and perfumes Grade 1 and Grade 2 is valid for five (5) years and may be renewed for equal and successive periods.

§1 The process of renewed registration of the product regularization must be requested in the first half semester of the last year of the five-year period of validity of the registration.

§2 The expiry of the of registration process shall be declared when it was not requested at the period referred to in this article.

Art. 23. In order to manufacture or import the products mentioned in this Resolution, the companies must have the Authorization License at Anvisa for the activities, and classes of products they want to market (personal care, cosmetic, and / or perfume) and must have License by the Sanitary Authority (local state or municipality licensing for their plants).

Art. 24. Compliance with Good Manufacturing Practices will be checked at the producer and / or importer establishment upon inspection conducted by the competent Sanitary Authority.

section II

Products Mechanisms Regularization

Art. 25. The products at Annex VIII, are subject to the registration procedure.

§ 1 The other toiletries, cosmetics, and perfumes are exempt from registration and are subject to procedure of prior notice before Anvisa.

§ 2. Prior notice is the administrative procedure to be applied to inform Anvisa the commercialization intention of a product exempt from registration through notification.

§ 3. The need to submit innovative products, not yet regulated to at the registration procedure will be established proper regulation.

CHAPTER IV

TRANSITIONAL AND FINAL PROVISIONS

Art. 26. The registration petitions already booked/filed at Anvisa that did not have its analysis already completed, and whose categories are not included in Annex VIII of this Resolution will be exempt from registration and its regularization will be disclosed as provided for in paragraph 2 of Art. 20.

Art. 27. The Grade 1 products which are already notified in accordance with Resolution RDC No. 343 of December 13, 2005 and Grade 2 products registered under Resolution RDC No. 211 of July 14, 2005 should be re-notified at the online automated system at the time that any change occur (on the label, on formulation, etc.) or on revalidation and must meet all requirements set forth in this resolution.

Art. 28. The regularized products in accordance with Resolutions RDC No. 211 of July 14 2005, RDC No. 343 of December 13, 2005 and RDC No. 04 of 30 January 2014 may be marketed until the expiration of the validity of the product, since duly revalidated (if it is the case).

Art. 29. ANVISA may establish other forms of petitioning, including no electronic formats, according to the interest of the administration.

Art. 30. Failure to comply with the provisions of this Resolution or in the other regulations related to toiletries, cosmetics, and perfumes will result in the cancellation of the regularization and disclosure at the ANVISA site, without prejudice to other actions or measures provided for in the legislation.

Art. 31. The authenticity and veracity of the information provided to ANVISA are the responsibility of the registration holder, and any irregularity detected by ANVISA, in violation of the relevant provisions of sanitary legislation, constitute a health violation, pursuant to the Law No. 6437 of August 20, 1977, without prejudice of the civil, administrative and criminal appropriate responsibilities, and will result in the cancellation of the product registration or the exemption from registration under this Resolution.

Art. 32 There are hereby revoked the ANVISA's Collegiate Board Resolutions RDC No. 211 of 14 July 2005 and Resolution RDC No. 343 of 13 December 2005 and Resolution RDC No. 04 of January 30 2014.

Art. 33. This Resolution shall enter into force 15 days from the date of its publication.

JAIME CESAR DE MOURA OLIVEIRA

ANNEX I Definition

I – toiletries (personal hygiene, personal care products), cosmetics and perfumes: they are preparations consisting of natural or synthetic substances, for external use on various parts of the human body, skin, capillary system, nails, lips, external genital organs, teeth and mucous membranes the oral cavity, with the exclusive or main purpose of cleaning them, perfuming them, changing their appearance and or correcting body odors and or protecting them or keeping them in good condition.

ANNEX II Classification of toiletries, cosmetics, and perfumes

1. Definition Products Grade 1: toiletries (personal hygiene, and personal care products), cosmetics, and perfumes are those products whose formulation complies with the definition adopted in item I of Annex I of his resolution and that are characterized by having basic or elementary properties, the proof of which is not initially required and do not require detailed information on their mode of use and its use restrictions, due to the intrinsic characteristics of the product, as mentioned on the indicative list "LIST OF GRADE 1 PRODUCTS TYPES" set out in item "I" in this section.

2. Definition Products Grade 2: toiletries (personal hygiene, and personal care products), cosmetics, and perfumes whose formulation complies with the definition adopted in item I of Annex I of this resolution and that they have specific indications, whose characteristics require proof of safety and / or effectiveness as well as information and care, mode and restrictions of use, as mentioned in the indicative list " GRADE 2 PRODUCTS TYPES" as defined in item "II" of this section.

3. The criteria for this classification were defined according to the probability of occurrence of unwanted effects due to inappropriate use of the product, its formulation, purpose of use, areas of the body that are intended and precautions to be observed when used.

I) LIST OF GRADE 1 PRODUCTS TYPES

1. Eau de Cologne Water Colony, Water Splashes, Water Scents, Perfume and Aromatic Extract.
2. Cuticle softener (non-caustic).
3. Mouth freshener.
4. Facial / body base (without sunscreen purpose).
5. Lipstick and lip gloss (without sunscreen purpose).
6. Blush / Rouge (without sunscreen purpose).
7. Conditioner / cream rinse / hair rinse (except with fall action, dandruff and / or other specific benefits to justify previous evidence).
8. Facial Concealer (without sunscreen purpose).
9. Cream, lotion and gel for the face (without sunscreen action for the skin and with exclusive purpose of hydration).
10. Body and / or facial exfoliating mechanical (peeling) cream, lotion, gel and oil.
11. Cream, lotion, gel and oil for the hands (without sunscreen action, without statement of individual protective action for work, as personal protective equipment - EPI (Equipamento de Proteção Individual) -and with the exclusive purpose of hydration and / or refreshing).
12. Legs cream, lotion, gels and oils (with the sole purpose of hydration and / or freshness).
13. Facial cleansing cream, lotion, gel and oil (except for acneic skin).
14. Body cream, lotion, gel and oil (except for special purpose action such as anti-stretch marks, or anti-cellulite; without skin photo protective action and with the sole purpose of moisturizing and / or refreshing).
15. Feet cream, lotion, gel and oil (with the sole purpose of hydration and / or freshness).
16. Liner for lips, eyes and eyebrows.
17. Demaquilant, makep remover.
18. Toothpaste (except the fluoride containing ones, the antiplaque action ones, anti decay, anti-tartar ones, with indication for sensitive teeth ones and with chemical bleaching).
19. Mechanical depilatory / epilatory.
20. Underarm deodorant (except with antiperspirant action).
21. Deodorant Colony.
22. Body deodorant (except intimate deodorant).
23. Feet deodorant (except with antiperspirant action).
24. Flavoring Mouthwash (except the fluoride containing ones and with antiseptic and anti-plaque actions).
25. Nail polish, enamels, varnish, glitter for nail, nail glitter.
26. Skin ribbons for mechanical removal of impurities.
27. Nail strengthener.
28. Kajal
29. Pencil for lips, eyes and eyebrows.
30. Moist toilettes, moist swipes, wet wipes, moistened handkerchief (except with antiseptic and / or other specific benefit actions that justify).
31. Facial tonic lotion (except for acne-prone skin).
32. Mask for eyelashes.
33. Body mask (with the sole purpose of cleansing, cleaning and / or moisturizing).
34. Facial mask (except for acne-prone skin, chemical peeling and / or other specific benefits that justify previous evidence).
35. Modeler / fixer for eyebrows.
36. Neutralizer for permanent (hair curl) and smoothing of hair.
37. Face Powder, compact powder (without sunscreen purpose).

38. Products for the bath / immersion: salts, oils, soft gels and bubble bath.
39. Products for shaving (except with antiseptic action).
40. Products to set, model, and / or beautifying the hair: fasteners, hairspray, tips repair, hair oil, glossy, mousses, creams and gels to model and lay the hair, hair restorer, hair and capillary humidifier mask.
41. Products for pre-shave (except with antiseptic action).
42. Post-shaving products, after-shaving products (except with antiseptic action).
43. Lip balm without sunscreen.
44. Nail polish remover.
45. Abrasive / mechanical exfoliation soap (except with antiseptic action or chemical exfoliation).
46. Facial and / or body soap (except with antiseptic action or chemical exfoliation).
47. Deodorant / deodorizing Soap (except with antiseptic action).
48. Nail Polish drier, enamel secant.
49. Eyeshadow, Shadow to the eyelids.
50. Talc / powder (except with antiseptic action).
51. Shampoo (except with anti-fall action, dandruff and / or other specific benefits justifying the previous evidence).
52. Conditioner Shampoo (except with anti-fall action, dandruff and / or other benefits specific that justify previous evidence).

3. Note: The exceptions mentioned in item "I) LIST OF GRADE 1 PRODUCTS TYPES " characterize Grade 2 products.

II) LIST OF LEVEL 2 PRODUCT TYPES

1. Hydrogen peroxide 10-40 volumes preparations (including creamy, except the products of medicinal use).
2. Underarm antiperspirant.
3. Feet antiperspirant.
4. Tan activator / accelerator.
5. Child lipstick and lip gloss.
6. Solar / Anti-solar Blocker.
7. Child blush / rouge
8. Suntan.
9. Suntan simulators.
10. Skin lightener.
11. Nail chemical bleaching.
12. Brightener for hair and body hair.
13. Children's Colony, Children's Eau de Cologne.
14. Anti-dandruff / Anti-fall Conditioner
15. Children's Conditioner.
16. Anti-caries toothpaste
17. Antiplaque dentifrice.
18. Anti decay, anti-tartar dentifrice.
19. Whitening / chemical bleaching toothpaste.
20. Toothpaste for sensitive teeth.
21. Children's toothpaste.
22. Chemical depilatory.
23. Hair bleaching.
24. Underarm antiperspirant deodorant.
25. Deodorant antiperspirant for the feet.
26. Deodorant for intimate use.
27. Antiplaque mouthwash.
28. Antiseptic Mouthwash.
29. Children's Mouthwash.

30. Anti-dandruff / anti-fall hair rinse.
31. Children's capillary rinse / wash.
32. Dye / color hair rinse.
33. Chemical scrub "peeling", chemical peeling .
34. Children's nail polish, enamel for children's nails.
35. Children's hair fixative.
36. Wet Wipes for infant hygiene.
37. Makeup with sunscreen.
38. Product of children cleaning / sanitizing.
39. Product for smoothing and / or dyeing.
40. Product for eyes area (except the makeup ones, and / or moisturizing action, and / or makeup remover).
41. Product to avoid nail biting.
42. Product to curl hair.
43. Product for acne-prone skin.
44. Product for wrinkles.
45. Protector product for children's skin.
46. Lip balm with sunscreen.
47. Sunscreen.
48. Children's sunblock.
49. Cuticle remover.
50. Chemical nicotine stain remover.
51. Insect repellent.
52. Antiseptic soap.
53. Children's Soap.
54. Intimate use soap.
55. Children's talc / starch.
56. Antiseptic talc / powder.
57. Temporary / progressive / permanent hair dye.
58. Capillary tonic / lotion.
59. Anti-dandruff / anti-fall shampoo.
60. Colorant shampoo.
61. Anti-dandruff / anti-fall conditioner shampoo.
62. Children's conditioner shampoo.
63. Children's shampoo.

ANNEX III Specific Technical Requirements for toiletries, cosmetics and perfumes

| Mandatory requirements | Documents to be held and to be submitted during company Inspection by (local) health authorities | Documents mandatory for the commercialization of the product (for the online regularization) | Observations |
|--|--|--|--|
| 1. Qualitative and quantitative Chemical Formula, or Formula Declaration | Yes | Yes | With all components specified by their INCI names and the amounts of each expressed in percentage (w / w) using the metric system. |
| 2. Function of ingredients | Yes | Yes | Quote the function of each component in the formula. |

| | | | |
|--|-------------------------|-----------------|---|
| 3. Bibliography and / or reference of the ingredients | Yes | Yes | Only when the component is not in the INCI nomenclature database, or is not listed at the approved substance list, including pertinent and relevant literature, including that relevant to efficacy and safety. |
| 4 Organoleptic and physicochemical Specifications of raw materials | Yes | No | |
| 5. Microbiological specifications of raw materials | Yes | No | Only when applicable |
| 6. Organoleptic and physicochemical specifications of the finished product | Yes | Yes | |
| 7. Microbiological specification of the finished product | Yes | Yes | Only when applicable |
| 8. Manufacturing Process | Yes | No | According the GMP legislation (A simple working flow diagram of the manufacturing process (no details needed)) |
| 9. Technical specifications of the packaging material | Yes | No | Packaging dimensions and resumed material specs. |
| 10. Product stability test results | Yes (Full test results) | Yes (summary) | This is a mandatory data to establish the product expiration/validity date (methodology protocol if necessary and conclusion).- |
| 11. Batch encoding system description | Yes | No | |
| 12. Label artwork of the label | Yes | Yes | Label text (full) in English and Portuguese Including information and warnings relating to the product including inserts or brochures |
| 13. Proof of product claims effectiveness | Yes | No | Test results showing the products label claims effectiveness |
| 14. In use safety data | Yes | No | Report including the methodology and results |
| 15. Intended use | Yes | Yes | When it is not implicit in the denomination of the product |
| 16. Original free sale | Yes (original) | Yes (certified) | According legislation |

| | | | |
|--|----------------|----------------------|---|
| certificate (1)) | | copy) | |
| 17. Licensing / authorization / Inscription of the company | yes | No | According legislation |
| 18. Qualitative and quantitative Chemical Formula, or Formula Declaration when imported and stamped at a Brazilian Consulate | Yes (original) | Yes (certified copy) | If this data is not already attached to the Free Sale Certificate |

(1) Free Sale Certificate: corresponds to the Certificate of Free Trade granted by the Sanitary Authority or the officially recognized bodies in the country of origin.

ANNEX IV

ADDITIONAL REQUIREMENTS FOR PERSONAL HYGIENE PRODUCTS, COSMETICS, AND PERFUMES IMPORTED MERCOSUR AND EXTRA-ZONE

1. Regularization of Products

1.1. The Responsible Companies by the Ownership of imported Toiletries, Cosmetics, and Perfumes (hereinafter Responsible Company) shall submit to the Health Authority a Product Registration request signed by the Legal Representative and the Technical Director, accompanied, among others, by the following documents:

a) Certificate of Free Trade (Free Sale Certificate) in the country of origin issued by the Sanitary Authority and stamped by the local Brazilian Consulate;

b) If the Certificate of Free Trade does not contain the qualitative and quantitative formula this should be attached, and signed by the Legal Representative and the Responsible Company Technical manager of the manufacturer and properly stamped at the Brazilian Embassy.

c) Proof of payment of the fees established by the Health Authority (Anvisa);

1.2. The Responsible Companies and Importing Companies should have additional information on the analytical level about the use and safety of the product to provide to the Health Authority if so required.

1.3. Labels, brochures (inserts) and packaging. The documentation will be accompanied by the label. Inserts and packaging of the product when they are used. This documentation may be provided by photocopies of them or corresponding transcriptions of the texts. If the original label does not contain the required information, it will be accepted the adequacy through an over-label or tag that contain the missing information.

1.4. It shall be stated that the ingredients of the formulation comply with national health regulations.

1.5. The deadline for the Sanitary Authority to opine on the requested regularization of toiletries, cosmetics, and perfumes will be 60 days.

ANNEX V**LABELING REQUIREMENTS FOR TOILETRIES, COSMETICS, AND PERFUMES****TECHNICAL REGULATION ON GENERAL MANDATORY LABELING FOR PERSONAL HYGIENE PRODUCTS, COSMETICS, AND FRAGRANCE****A) OBJECTIVE**

Establish the necessary information to be included on the labels of toiletries, cosmetics, and perfumes, concerning their use, as well as all the necessary indication of the product.

B) DEFINITIONS

- 1 Primary Packaging: wrap or container that is in direct contact with the products.
- 2 Secondary Packaging: the packaging is intended to contain the primary packaging or the primary packagings.
- 3 Label: printed or lithographed identification and painted or inscribed sayings, glued under pressure label or other applied wordings, directly on the containers, packages, wrappers, wraps or any other packaging protector.
- 4 Brochure of Instructions: printed text accompanying the product, containing additional information.
- 5 Name / Group / Type: product designation to distinguish it from others, even though from the same company or manufacturer of the same type, quality or nature.
- 6 Brand: element that identifies one or more products from the same company or manufacturer that distinguishes them from other companies' or manufacturers' products, according to the industrial property rights legislation.
- 7 Origin / Source: place of production or manufacture of the product.
- 8 Lot or batch: Quantity of a product in a manufacturing cycle, properly identified, whose main characteristic is the homogeneity.
- 9 Shelf Life: Time that the product retains its properties when kept in the original packaging and undamaged, under appropriate conditions of storage and use.
- 10 Registry holder: legal entity or equivalent denomination defined in the national legislation which has registration of toiletries record, cosmetics, and perfumes
- 11 Producer / Manufacturer: company that has the necessary facilities for the manufacture / preparation of toiletries, cosmetics and perfumes.
- 12 Importer: legal entity or equivalent denomination defined in national law, responsible for the introduction into a country the, foreign toiletries, cosmetics, and perfumes.
- 13 Product Registration Number: corresponds to the company identification number and the number of resolution for the ~~or~~ product marketing authorization.
- 14 Ingredients / Composition: qualitative description of the components of the formula by its generic name, using the coding of substances established by the International Nomenclature of Cosmetic Ingredients (INCI).
- 15 Warnings and Use Restrictions: they are the mandatory information set out at ~~in~~ the lists of substances when there exist and to inform the presence of them at the label and those fixed at the Annex V of this resolution "Labeling Requirements For Toiletries, Cosmetics and Perfumes".

C) GENERAL LABELING REQUIREMENTS

| Ref. | ITEM | Packaging |
|------|--|-----------------------|
| 01 | Product and group name (If it is not implicit in the name) | Primary and Secondary |

| | | |
|----|--|-----------------------|
| 02 | Brand | Primary and Secondary |
| 03 | Product Registration Number | Secondary |
| 04 | Lot or Batch number | Primary |
| 05 | Expiration/validity date | Secondary |
| 06 | Product / net content | Secondary |
| 07 | Country of Origin | Secondary |
| 08 | Manufacturer / Importer / Regularization Holder | Secondary |
| 09 | Manufacturer / Importer / Holder name and address | Secondary |
| 10 | Instruction of how to use the product (when not implicit on the name of the product) | Primary or Secondary |
| 11 | Warning of use and product risks (if it is the case) | Primary and Secondary |
| 12 | Specific label | Primary and Secondary |
| 13 | Product chemical formula (qualitative only) | Secondary |

D) REMARKS

- 1 - When there is no secondary packaging all the required information must appear on the Primary Package.
- 2 - The Method of Use may be presented at an annexed brochure. In this case, it should be indicated at the Primary packaging: - "See attached brochure."
- 3 - When the package is small and does not allow the inclusion of warnings and restrictions of use, they may be annexed in a brochure. It must be indicated on the primary packaging: - "See attached brochure."

ANNEX VI

TECHNICAL REGULATION ON LABELING FOR SPECIFIC PERSONAL HYGIENE PRODUCTS, COSMETICS, AND FRAGRANCE

a) AEROSOLS

- 1 "Inflamável. Não pulverizar perto do fogo" (Flammable. Do not spray near the fire);
- 2 "Não perfurar, nem incinerar" (Do not puncture or incinerate);
- 3 "Não expor ao sol nem a temperaturas superiores a 50 °C" (Do not expose to sunlight or to temperatures above 50 ° C);
- 4 "Proteger os olhos durante a aplicação" (Protect eyes during application);
- 5 "Manter fora do alcance das crianças" (Keep out of the reach of children).

b) NEUTRALIZING, PRODUCTS FOR CURLING AND SMOOTHING THE HAIR:

- 1 "Não aplicar se o couro cabeludo estiver irritado ou lesionado" (Do not apply if scalp is irritated or injured);
- 2 "Manter fora do alcance das crianças" (Keep out of reach of children).

c) HAIR LIGHTENERS AGENTS AND HAIR DYES:

- 1 "Pode causar reação alérgica. Fazer a Prova de Toque (descrever)" (May cause allergic reactions. Do the Contact Test (describe mode of action, i.e., how to perform));

2 “Não usar nos cílios e sobrancelhas” (Do not use on eyelashes and eyebrows);

3 “Não aplicar se o couro cabeludo estiver irritado ou lesionado” (Do not apply if scalp is irritated or injured);

4 “Em caso de contato com os olhos, lavar com água em abundância” (In case of contact with eyes, rinse with plenty of water);

5 “Manter fora do alcance das crianças” (Keep out of the reach of children).

d) HAIR DYES WITH LEAD ACETATE:

1 “Não aplicar se o couro cabeludo estiver irritado ou lesionado” (Do not apply if scalp is irritated or injured);

2 “O uso inadequado pode provocar intoxicação por absorção de chumbo” (Improper use can cause lead poisoning absorption);

3 “Aplicar somente no couro cabeludo (cabelos)” (Apply only on the scalp (hair));

4 “Depois do uso, lavar as mãos com água em abundância para evitar a ingestão acidental” (After use, wash hands with plenty of water to prevent accidental ingestion);

5 “Manter fora do alcance das crianças” (Keep out of the reach of children).

e) DEPILATORY AND EPILATORY PRODUCTS:

1 “Não aplicar em áreas irritadas ou lesionadas” (Do not apply to irritated or damaged areas);

2 “Não deixar aplicado por tempo superior ao indicado nas instruções de uso” (Do not leave applied for longer than the time indicated in the instructions of use);

3 “Não usar com a finalidade de se barbear” (No use for the purpose of shaving);

4 “Em caso de contato com os olhos, lavar com água em abundância” (In case of contact with eyes, rinse with plenty of water);

5 “Manter fora do alcance das crianças” (Keep out of the reach of children).

f) TOOTHPASTES AND MOUTHWASH WITH FLUORIDE:

1 Present the name of the fluorine compound used and its concentration in ppm (parts per million);

2 Present the mode of use, when necessary;

3 “Não usar em crianças menores de 06 anos.” (Do not use in children under 06 years. (Only for mouthwashes)).

g) ANTIPERSPIRANTS / ANTIPERSPIRANT PRODUCTS:

- 1 “Usar somente nas áreas indicadas” (Use only on the indicated areas);
- 2 “Não usar se a pele estiver irritada ou lesionada” (Do not use if skin is irritated or injured);
- 3 “Caso ocorra irritação e/ou prurido no local da aplicação, suspender o uso imediatamente” (In the event of irritation and / or itching at the application site, discontinue use immediately).

h) HAIR TONICS:

- 1 “Em caso de eventual irritação do couro cabeludo, suspender o uso” (In the event of irritation of the scalp, discontinue use).

ANNEX VII

RESPONSIBILITY DISCLAIMER (This disclaimer is automatic generated during the online product regularization)

The company, (report **the name of the company**), duly authorized by the National Agency of Health Surveillance-ANVISA, under the number (report **the authorization number of operation**), herein represented by its Technical Responsible person and its Legal Representative, declare that the product (report **the name of the product and its brand**) meets the regulations and other legal requirements for the process control and finished product ~~finished~~ and other technical parameters relating to the Good Manufacturing Practices relevant to the product category.

The company states that have supporting data that proves the safety and efficacy, the proposed purpose of the product, and that this is not a health hazard when used in accordance with the instructions for use and other measures contained at ~~in~~ the product sales package during its period of validity.

The company takes full responsibility before the Anvisa that the product meets the specific technical requirements set out in the current legislation, as well as the lists of substances, the regulation for labeling and the correct classification of the product.

The company states that the labeling does not contain indications and therapeutic mentions, nor ~~or~~ denominations and indications that lead to error, mistake or confusion related ~~as~~ to its origin, composition, purpose or safety.

The company acknowledges that the regularized product is subject to Audit, Market Monitoring and inspection registration by the competent health authority and being found any irregularity, the product will be canceled, without prejudice to the proper civil, administrative and criminal responsibilities.

The undersigned take full responsibility before this agency , that the failure to obey the current regulations and their updates, constitutes health violation, subjecting the offenders to the penalties provided by the law.

(Signatures below)

(Name)
Signature

(Name)
Signature

Company Legal Representative
Director (CEO)

Technical Manager/Responsible
Manager

ANNEX VIII
GRADE 2 PRODUCTS SUBJECT TO REGISTRATION

1. Children lipstick and lip gloss.
2. Solar Blocker / anti-solar.
3. Children Blush / rouge.
4. Suntan.
5. Children's Colony, Children Eau de Cologne.
6. Children Conditioner.
7. Children Toothpaste.
8. Child Mouthwash.
9. Children's hair rinse.
10. Enamel for children nails, Children Nail Polish.
11. Children's hair fixative.
12. Moistened tissues, wet wipes for child care.
13. Product of child cleaning / sanitizing.
14. Product for hair smoothing and / or dye.
15. Product for skin protection of children's.
16. Children's sunblock.
17. Sunscreen.
18. Insect repellent.
19. Children's Soap.
20. Children Talc / starch.
21. Children Conditioner Shampoo.
22. Children Shampoo.

23. Hands Antiseptic Gel

ATTENTION: This is a quasi verbatim translation from the original RDC 07/2015, issued only in Portuguese language by ANVISA. The translation was done by Mr. Emerson Gonalez, a reputable Regulatory Affairs Consultant who may be contacted at cell phone: (+55)-11-97222-7707 / atvs.regulatory@gmail.com