

New procedure involving registration of cosmetics is published by ANVISA, Resolution of ANVISA'S Board of Directors - RDC #7/2015

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In Official Gazette of February 11, 2015, ANVISA published a new resolution of their Collegial Board of Directors, **RDC #7/2015**, which updates the technical requirements for the regulation of personal hygiene products, cosmetics and perfumes, in order to simplify and expedite the treatment given to this category of products in the country. The resolution came into force on February 25, 2015.

In Brazil, cosmetics are classified by ANVISA as products grades 1 or 2. Grade 1 products are characterized by having basic properties, which do not require further characterization or detailed information regarding their use and restrictions. On the other hand, grade 2 products have specific indications, which characteristics demand attesting safety and/or efficacy, as well as information regarding care, use and restrictions.

As of the publication of RDC #4/2014, the procedures regarding the regulation of cosmetics had already been defined in order to establish the Electronic Automation System of ANVISA as the basis for all activities comprehending notification, registration and corresponding alterations regarding this product's category.

Thus, the electronic platform was launched to meet the expectations of improvement and streamlining the Agency's working methods and, likewise, facilitate the preparation of the processes for the registration of cosmetics classified as grade 2, previously performed in physical means by the industries, requiring therefore having the protocol in hard copies.

New **RDC #7/2015** is the result of several discussions within ANVISA's Collegial Board of Directors (DICOL) aiming to improve the provisions of RDC #4/2015, especially when it refers on how to petition regarding grade 1 and grade 2 products.

The main changes implemented by **RDC #7/2015** are:

- 1) Only products listed in Annex VIII of the attached resolution (infantile products, sunscreens, suntan lotions, insect repellents, hair dyeing and/or hair straightening products, and antiseptic hand gel) are subject to the registration proceedings;
- 2) The remaining products with grades 1 and 2 will be exempt from registration and subject only to an electronic notification procedure to ANVISA prior to its commercialization;
- 3) As for personal hygiene products, cosmetics and perfumes grades 1 or grade 2, which are exempt from registration, notification of their regulation shall be ensured by means of electronic disclosure at ANVISA's website;
- 4) As for grade 2 personal hygiene products, cosmetics and perfumes subject to registration, notification of their regulation shall be ensured by means of publication in the Official Gazette.

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RDC #7/2015 not only represents a step forward in simplifying the registration procedures of personal hygiene products, cosmetics and perfumes, but also enables ANVISA to focus their analysis on products of a higher risk.

However, the new resolution does not alter the parameters and safety requirements for these products' category. The control of these products will be carried out through procedures which include periodic and random verification of processes, in addition to market monitoring with the verification and analysis of what is on the shelves available to the consumer.

Attached you will find copy of ANVISA's resolution, **RDCs #7/2015**. Should you have any queries and/or wish to receive more details hereon, please do not hesitate to contact us and we will be glad to assist you in this respect.

RESOLUTION - RDC N° 7th, OF FEBRUARY 10th, 2015

Provides for the technical requirements for regularization of personal hygiene products, cosmetics and perfumes, and establishes other provisions.

The Collegial Board of the National Health Surveillance Agency (ANVISA), in exercise of the powers conferred by items III and IV, of Article 15 of Law No. 9,782, dated January 26, 1999, item V, and §§ 1st and 3rd of Article 5 of the Bylaw approved in terms of Annex I of ANVISA's Ordinance No. 650, of May 29, 2014, in view of the dispositions of items III, of Article 2, III and IV, of Article 7 of Law No. 9,782 of 1999, Article 35 of Decree No. 3,029, of April 16, 2009 and the Program for Enhancement of Regulation Process of the Agency, established by Ordinance No. 422, of April 16, 2008, in a meeting held on October 9, 2014, adopts the following Board Resolution and I, the Director-President, determine its publication:

Article 1 – It is hereby approved the Technical Regulation, which establishes the definition, classification, technical requirements, labeling and electronic procedure for regularization of personal hygiene products, cosmetics and perfumes pursuant to this Resolution.

Article 2 – This Regulation incorporates to the National Legal System Resolutions GMC MERCOSUR No. 110/94 “Definition of Cosmetic Products”, 07/05 “Classification of Personal Hygiene Products, Cosmetics and Perfumes”, 26/04 “Specific Technical Requirements for Personal Hygiene Products, Cosmetics and Perfumes”, 36/04 “General Mandatory Labeling for Personal Hygiene Products, Cosmetics and Perfumes”, 36/99 Specific Labeling for Personal Hygiene Products, Cosmetics and Perfumes”, and 24/95 “Requirements for the Registration of Mercosur Cosmetics Products and Extra-Zone and for the Qualification of Representative Companies Holder of the Registration in the State/Receiving Part and Importers”.

CHAPTER I

INITIAL PROVISIONS

Section I

Purposes

Article 3 - This Regulation has the purpose of updating the required procedures for regulation of personal hygiene products, cosmetics and perfumes by simplifying processes aiming at improving information quality and speed of analysis.

Section II

Coverage

Article 4 – This Regulation applies to personal hygiene products, cosmetics and perfumes classified as Grade 1 and Grade 2, in accordance with the definitions included in Annex I and II of this Resolution.

Article 5 – The specific technical requirements for personal hygiene products, cosmetics and perfumes are hereby established, in accordance with Annex III of this Resolution.

Article 6 – The additional requirements for personal hygiene products, cosmetics and perfumes imported from Mercosur and extra-zone are hereby established, in accordance with Annex IV of this Resolution.

Article 7 – The requirements for general mandatory labeling for personal hygiene products, cosmetics and perfumes are hereby established, in accordance with Annex V of this Resolution.

Article 8 – The requirements for specific labeling of personal hygiene products, cosmetics and perfumes are hereby established, in accordance with Annex VI of this Resolution.

Article 9 – Products intended to be room odorizers are classified as personal hygiene products, cosmetics and perfumes Grade 1.

Article 10 – The product holder must have substantive supporting data attesting to the quality, safety and efficacy of its products and the suitability of what is stated in the labels, as well as the technical requirements established in Annex III of this Resolution, which should be submitted to the health surveillance agencies whenever requested or during inspections. It should also ensure that the product is not a risk to health when used in accordance with the instructions for use and other measures contained in the product sales package during its expiration term.

Sole paragraph – The company should attach to the dealing the Statement of Responsibility, duly signed by the Technician in Charge and the Company's Legal representative, pursuant to Annex VII.

Article 11 – Personal hygiene products, cosmetics and perfumes should meet the dispositions:

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

II- List of colorant substances allowed for personal hygiene products, cosmetics and perfumes – Resolution - RDC No. 44, of August 9, 2012 and its updates;

III- List of substances the personal hygiene products, cosmetics and perfumes should not contain, except under established conditions and restrictions – Resolution - RDC No. 3, of January 18, 2012 and its updates;

IV- List of ultraviolet filters allowed for personal hygiene products, 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.

Article 12 – Personal hygiene products, cosmetics and perfumes classified as Grade 1 should be in accordance with the current regulations and also the following criteria:

I- They should not contain substances included in the Restrictive List of Resolution - RDC No. 3, of January 18, 2012 and its updates, which are specific to products classified as Grade 2, except for the cases in which the presence of the substance in the formulation does not change the purpose of the product and not mischaracterizes its classification as Grade 1;

II- They must not contain substances included in the Ultraviolet Filter List to the protection of the skin against the damaging effects of sunlight, contained in Resolution - RDC No. 47, of March 16, 2006 and its updates, since the presence of these substances characterizes a Grade 2 product;

Article 13 – Packaging in the form of aerosols will not be allowed to talc.

Article 14 – The vessels of the products presented in the form of an aerosol, the glass being wrapped by plastic material, should contain small holes to the output of the content in case of breakage.

Article 15 – The vessels of the products pressed in the form of aerosols cannot not have a capacity greater than 500 (five hundred) milliliters.

Article 16 – The provisions of this Resolution does not preclude compliance with other regulations provided for in health legislation, relevant to personal hygiene products, cosmetics and perfumes.

Article 17 – The labeling of personal hygiene products, cosmetics and perfumes should not contain therapeutic indications, or denominations and indications inducing error, mistake, or confusion regarding its provenience, origin, composition, purpose, or safety.

Article 18 – The labeling of Grade 1 and Grade 2 personal hygiene products, cosmetics and perfumes should have the Company Working Authorization number - AFE and the process number in the product label, generated on ANVISA system, corresponding to the registration number.

§ 1. For Grade 1 and Grade 2 products, exempt from registration, marketing can occur after publication in the ANVISA website.

§ 2. For Grade 2 products, subject to Registration, marketing can only occur after the grant of registration is published in the Official Gazette.

CHAPTER II

OTHER OBLIGATIONS ABOUT LABELING

Article 19 – Besides the advices provided in Annex VI of this Resolution, the following statements should be mandatorily added in first and second packaging:

I- AEROSOLS: “Avoid inhaling of this product.”

II- NEUTRALIZERS, PRODUCTS TO CURL AND STRAIGHTEN HAIR: “This solution should only be used for its intended purpose, any other use is HARMFUL.”

III- HAIR WHITENING AGENT AND HAIR DYES: The label of hair dyes and whitening agents having substances able to cause severe or chronic poisoning should have the warnings: “WARNING. It contains substances able to cause rashes on some people. Before use it, do the touch test.”

IV- TANNER SIMULATORS: The label of the products intended to simulate tanning of the skin should have the warning “Warning: it does not protect against sun damages.”

CHAPTER III

PROCEDURES FOR REGULATION

Section I

Electronic Automation System

Article 20 – It is hereby instituted the electronic procedure for the Regulation of Grade 1 and Grade 2 personal hygiene products, cosmetics, and perfumes before ANVISA.

§ 1. Sanitary regulations for the personal hygiene products, cosmetics, and perfumes from now on are performed only electronically, through ANVISA website.

§ 2. The publication of regulation of Grade 1 personal hygiene products, cosmetics, and perfumes exempt from registration will be made by means of disclosure at ANVISA website.

§ 3. The publication of regulation of Grade 2 personal hygiene products, cosmetics, and perfumes regulation will be made at the Official Gazette.

§ 4. Guidance needed to the electronic procedure for the regulation of personal hygiene products, cosmetics, and perfumes is available at ANVISA website.

Article 21 – Documents generated at the end of the electronic procedure must be kept in the company.

Sole paragraph – The Statement of Responsibility must be signed by the Technician in Charge and by the company's Legal Representative, completing all documentation related to the product.

Article 22 – Grade 1 and Grade 2 personal hygiene products, cosmetics, and perfumes regulation expires in 5 (five) years and may be revalidated for equal and successive terms.

§ 1. The revalidation of product regulation process should be requested in the first semester of the last year of the five years expiration term.

§ 2. It will be declared the forfeiture of the process of which revalidation is not requested in the term referred to in this article.

Article 23 – To manufacture or import the products dealt with in this Resolution, companies should have Working License granted by ANVISA for activities and product classes they wish to market (personal hygiene product, cosmetics, and/or perfume) and must have License granted by the proper Sanitary Health Authority.

Article 24 – The compliance with Good Manufacturing Practices shall be checked in the manufacturing facility and/or importer's facility by means of inspection performed by the proper Sanitary Health Authority.

Section II

Product Regulation Mechanisms

Article 25 – Products set forth in Annex VIII are subject to the Registration procedure.

§ 1. The other personal hygiene products, cosmetics and perfumes are exempt from registration and are subject to prior notification procedure at ANVISA.

§ 2. Prior communication is the administrative procedure to be applied to inform ANVISA by means of a notification regarding intention of marketing a product exempt from registration.

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

CHAPTER IV

TRANSITORY AND FINAL PROVISIONS

Article 26 – Registration petitions already filed with ANVISA with an incomplete analysis, and of which categories are not included in Annex VIII of this Resolution will be exempt from registration and their regulation will be disclosed according to the provisions of 2nd paragraph of Article 20.

Article – Grade 1 products notified in accordance with Resolution RDC No. 343, of December 13, 2005, and Grade 2 products registered in accordance with Resolution RDC No. 211, of July 14, 2005 must be registered again in the automation system, at the time any change or revalidation occur and they must meet all requirements set forth in this resolution.

Article 28 – The products regulated in accordance with Resolutions RDC No. 211, of July 14, 2005, Resolution RDC No. 343, of December 13, 2005 and Resolution RDC No. 4, of January 30, 2014 may be marketed until product expiration, provided that they are duly revalidated.

Article 29 – ANVISA may establish other forms of petitioning, including in non-electronic form, according to the administration's interest.

Article 30 – Failure to comply with the provisions of this Resolution or other regulations related to personal hygiene products, cosmetics and perfumes will result in the cancellation of regulation and its disclosure at ANVISA website, without prejudice to other actions or measures provided for in legislation in force.

Article 31 – The authenticity and accuracy of information provided to ANVISA are responsibility of the registration holder, and any irregularity detected by ANVISA, in disagreement with the provisions of pertinent healthy legislation, is a health violation,

pursuant to Law No. 6,437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal responsibilities, and it will result in cancellation of the registration, or regulation of product exempted from registration pursuant to this Resolution.

Article 32 – The following Board Resolutions are hereby revoked: RDC No. 211, of July 14, 2005 and RDC No. 343, of December 13, 2005 and RDC No. 4, of January 30, 2014.

Article 33 – This Resolution shall enter into force within 15 days counted as from its publication date.

JAIME CESAR DE MOURA OLIVEIRA

ANNEX I

Definitions

I - Personal Hygiene Products, Cosmetics, and Perfumes: are preparations made of natural or synthetic substances, of external use in several parts of the human body, skin, hair system, nails, lips, external genital organs, teeth, and mouth mucous membranes, with the exclusive or main purpose of their cleaning, perfuming, changing their appearance, and/or solve body smells and/or protect them or keep them in good health.

ANNEX II

Classification of personal hygiene products, cosmetics, and perfumes

1. Definition of Grade 1 Products: are personal hygiene products, cosmetics, and perfumes, of which formulation fulfils the definition set forth in Annex I, item I, of this Resolution, and are characterized by having basic or elementary properties, which substantiation is not needed at first, and do not require detailed information regarding their way of using and their use restriction, due to intrinsic characteristics of the product, as mentioned on the indicative list "LIST OF GRADE 1 PRODUCT TYPES" set forth in item "I", in this section.

2. Definition of Grade 2 Products: are personal hygiene products, cosmetics, and perfumes, of which formulation fulfils the definition set forth in Annex I, item I, of this Resolution, and are characterized by having specific indications, and their characteristics demand a safety and/or efficiency substantiation, as well as information regarding, care, and use mode and restriction, as mentioned on the indicative list "LIST OF GRADE 2 PRODUCT TYPES" set forth in item "II", in this section.

3. The criteria for this classification were defined according to occurrence probability of non-desirable effects due to the improper use of the product, its formulation, use purpose, body areas of destination, and precautions to be observed when using it.

I) LIST OF GRADE 1 PRODUCT TYPES

1. Eau de cologne, Eau de Perfume, Perfume and Aromatic Extract.
2. Cuticle softener (non-caustic).
3. Mouth Flavoring.
4. Face/body Foundation (without photoprotective purpose).
5. Lipstick and Lip Gloss (without photoprotective purpose).
6. Blush/Rouge (without photoprotective purpose).

7. Conditioner/rinse cream/hair rinse (except those with anti-hair loss, Anti-dandruff action, and/or other specific benefits justifying prior substantiation).
8. Concealer (without photoprotective purpose).
9. Facial cream, lotion, and gel (without skin photoprotective purpose and with exclusive purpose of hydration).
10. Cream, lotion, gel and oil for body and/or facial mechanical peeling.
11. Hand cream, lotion, gel and oil (without photoprotective action, without indication of single protection action for labor, such as personal protection equipment - PPE - and with exclusive purpose of hydration and/or freshness).
12. Leg cream, lotion, gel, and oil (with exclusive purpose of hydration and/or freshness).
13. Cream, lotion, gel, and oil for facial cleaning (except for acne skin).
14. Body cream, lotion, gel, and oil (except those with specific purpose of anti-stretch marks, or anti-cellulitis, without skin photoprotective action and exclusive purpose of hydration and/or freshness).
15. Feet cream, lotion, gel, and oil (with exclusive purpose of hydration and/or freshness).
16. Lips, eyes and eyebrows liner.
17. Makeup remover.
18. Toothpaste (except those with Fluor, with anti-plaque, anti-cavity, anti-tartar, actions, indicated for sensitive teeth and chemical whiteners).
19. Mechanical depilatory/epilatory.
20. Armpit deodorant (except those with antiperspirant).
21. Deodorant cologne.
22. Body deodorant (except intimate deodorant).
23. Feet deodorant (except those with antiperspirant action).
24. Flavored mouth rinsing (except those with Fluor, anti-septic and anti-plaque action).
25. Nail polisher, lacquer, nail gloss.
26. Stripes for mechanical removal of skin impurities.
27. Nail strengthener.
28. Kajal.
29. Shading pencil for the lips, eyes, and eyebrows.
30. Wet wipes (except those with anti-septic and/or other specific benefits which justify prior substantiation).
31. Facial tone lotion (except for acne skin).
32. Mascara.

33. Body mask (with exclusive purpose of cleaning and/or hydration).
34. Facial mask (except those for acne skin, chemical peeling, and/or other specific benefits, which justify prior substantiation).
35. Eyebrow modeler/Fixer.
36. Neutralizer for permanent and smoothing.
37. Facial powder (without photoprotective purpose).
38. Products for bath/immersion: salts, oils, gelatinous capsules, and bubble bath.
39. Products for shaving (except those with anti-septic action).
40. Products for fixing, modeling, and/or to beautify hair: fixers, lacquers, tip fixer, hair oil, fixing gel, mousses, modeling and hair straighter creams and gels, hair restaurateur, hair mask and hair humidifier.
41. Products for pre-shaving (except those with anti-septic action).
42. Products after shaving (except those with anti-septic action).
43. Lip balm without sunscreen.
44. Nail polish remover.
45. Abrasive soap/peeling (except those with anti-septic action or chemical peeling).
46. Facial and/or body soap (except those with anti-septic or chemical peeling action).
47. Deodorant soap (except those with anti-septic action).
48. Nail Polisher dryer.
49. Shadow for eyelids.
50. Talc/powder (except those with anti-septic action).
51. Shampoo (except those with anti-hair loss, Anti-dandruff action, and/or other specific benefits, which justify prior substantiation).
52. Shampoo conditioner (except those with anti-hair loss, Anti-dandruff action, and/or other specific benefits, which justify prior substantiation).

3. Remarks: Exceptions mentioned in item "I) LIST OF GRADE 1 PRODUCT TYPES" characterize Grade 2 products.

II) LIST OF GRADE 2 PRODUCT TYPES

1. Hydrogen peroxide 10 to 40 degrees (including creamy except those products of clinical use).
2. Armpit antiperspirant.
3. Feet antiperspirant.
4. Tanning activator/accelerator.
5. Lipstick and lip gloss for children.
6. Sunblock/anti-sun.
7. Blush/ rouge for children.

8. Suntan lotion.
9. Simulation suntan lotion.
10. Skin whitening.
11. Chemical nail whitening.
12. Hair and body hair whitening.
13. Cologne for children.
14. Anti-dandruff/anti-hair loss conditioner.
15. Conditioner for children.
16. Anti-cavity toothpaste.
17. Anti-plaque toothpaste.
18. Anti-tartar toothpaste.
19. Whitener Toothpaste/Chemical tooth whitener.
20. Toothpaste for sensitive tooth.
21. Toothpaste for children.
22. Chemical depilatory.
23. Hair bleach.
24. Armpit deodorant antiperspirant.
25. Feet deodorant antiperspirant.
26. Intimate deodorant.
27. Anti-plaque mouth rinsing.
28. Anti-septic mouth rinsing.
29. Mouth rinsing for children.
30. Anti-dandruff/anti-hair loss wash.
31. Hair rinse for children.
32. Coloring/toning hair rinse.
33. Chemical peeling.
34. Nail polisher for children.
35. Hair fixer for children.
36. Wet wipes for children hygiene.
37. Makeup with sunscreen.
38. Cleaning product for children.
39. Product to smooth and/or dye the hair.
40. Product for the eye (except those of makeup and/or moisturizing action and/or makeup remover).
41. Product to avoid nail biting.
42. Product to wave hair.
43. Product for acne skin.

44. Product for wrinkles.
45. Product protector for children skin.
46. Lip balm with sunscreen.
47. Sunscreen.
48. Sunscreen for children.
49. Cuticle Softener.
50. Nicotine chemical mark remover.
51. Insect repellent.
52. Anti-septic soap.
53. Soap for children.
54. Soap for intimate use.
55. Talc/starch for children.
56. Anti-septic talc/powder.
57. Temporary/progressive/permanent hair dye.
58. Hair tonic/lotion.
59. Anti-dandruff/anti-hair loss shampoo.
60. Coloring shampoo.
61. Anti-dandruff/anti-hair loss shampoo conditioner.
62. Shampoo conditioner for children.
63. Shampoo for children.

ANNEX III

Specific technical requirements for personal hygiene products, cosmetics, and perfumes

Mandatory Requirements	In the company, available to the competent authority	Submitted for product trade authorization	Remarks
1. Quali-quantitative formula	X	X	All its components specified under their INCI names and the amounts expressed on a percentage basis (p/p) by the metrical decimal system.
2. Function of the ingredients contained in the formula	X	X	Quote the function of each ingredient contained in the formula
3. Ingredient bibliography and/or reference	X	X	Only when the ingredient is not included in the INCI

			nomenclature or it does not fit in the list of approved substances, include bibliography about it and relevant literature, including information related to efficiency and safety.
4. Organoleptical and physical-chemical technical specifications of raw materials	X		
5. Microbiological specifications of raw materials	X		When applicable.
6. Organoleptical and physical-chemical technical specifications of finished product.	X	X	
7. Microbiological specifications of finished product	X	X	When applicable, as per legislation in force
8. Manufacturing Process	X		According to Standards of Good Manufacturing Practices and Control provided for in legislation.
9. Technical specifications of packaging material	X		
10. Stability Data	X (complete)	X (summary)	Methodology and conclusions certifying said expiration date.
11. Batch Coding System	X		Information to interpret the coding system.
12. Art Project of Stamp or labeling	X	X	Data and warning information regarding product according to legislation in force.
13. Substantive data of benefits assigned to the product (efficiency substantiation)	X		Whenever the product benefit nature justifies it and whenever it is on label.
14. Use safety data (safety substantiation)	X		
15. Product Purpose	X	X	The product purpose when it is not specified in its name.
16. Consularized free Sale Certificate (1)	X (original)	X (certified copy)	According to legislation in force
17. Register/Company Authorization/Facility Enrollment Certificate	X		According to legislation in force
18. Consularized imported product formula	X (original)	X (certified copy)	If it is not attached to the Free Sale Certificate, according to legislation in force.

(1) Free Sale Certificate: correspond to the Free Marketing Certificate granted by the proper Sanitary Health Authority or by Officially Recognized Organizations in the country of origin.

ANNEX IV

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

1. Products Regulation

1.1. The Companies in charge of the ownership of imported Personal Hygiene Products, Cosmetics, and Perfumes registration (hereinafter Company in Charge) should present to the Sanitary Authority a Product Registration Request signed by the Legal representative and the Technician in Charge, with, not limited to, the following documentation:

a) Free Marketing Certificate in the country of origin, issued by the proper Sanitary Health Authority and duly consularized;

b) If the Free Marketing Certificate does not have the quali-quantitative formula it should be attached, signed by the Legal representative and by the Manufacturing Company's Technician in Charge and duly and consularized.

c) Proof of payment of fees set forth by the Sanitary Authority;

1.2. The Companies in Charge and the Importing Companies should have additional information on an analytical level regarding the product safety to provide for the Sanitary Authority, if required.

1.3. Labels, prospectus, and packaging. Documentation must be accompanied with the label. Product prospectus and packaging must be attached when they were used. This documentation can be presented by means of copies thereof or indication of the corresponding texts. If the original label does not contain the required information, an adaptation shall be accepted by means of an over-label or tag having the missing information.

1.4. It shall be declared that the formulation ingredients fulfill the national sanitary regulations.

1.5. The maximum term for the Sanitary Authority to present a response regarding the regulation of the submitted personal hygiene products, cosmetics, and perfumes shall be 60 days.

ANNEX V

Requirements for labeling of Personal Hygiene Products, Cosmetics, and Perfumes

TECHNICAL REGULATION REGARDING GENERAL MANDATORY LABELING FOR PERSONAL HYGIENE PRODUCTS, COSMETICS, AND PERFUMES

A) PURPOSE

Establish the essential information that must be on the labeling of personal hygiene products, cosmetics, and perfumes, in what concerns its use, as well as all indication needed about the product.

B) DEFINITIONS

1 Primary Packaging: wrapping or recipient in direct contact with the products.

2 Secondary Packaging: the packaging designed to contain the primary packaging or primary packages.

3 Label: pressed or lithographed identification, as well as painted or recorded text, decal under pressure or others, applied directly on recipients, packages, casings, wrappers, or any other packaging protector.

4 Instructions Leaflet: printed text accompanying the product, having complementary information.

5 Name/Group/Type: product design for distinguishing it from others, even from the same company or manufacturer, of the same species, quality, or nature.

6 Brand: element identifying one or several products from the same company or manufacturer and distinguishing them from products of other companies or manufacturers, as per industrial property legislation.

7 Origin: Product industrialization or production place.

8 Batch or Departure: Amount of a product in a manufacturing cycle, duly identified, of which main characteristic is homogeneity.

9 Shelf Life: time in which the product keeps its proprieties, while kept at the original packaging and without damages, in adequate storage and use conditions.

10 Registration holder: Corporation or similar denomination defined in the National Legal System that has the registration of personal hygiene products, cosmetics, and perfumes.

11 Developer/Manufacturer: company that has the facilities needed for manufacturing/developing personal hygiene products, cosmetics, and perfumes.

12 Importer: Corporation or similar denomination defined in the National Legal System in charge of the introduction of Foreign Personal Hygiene Products, Cosmetics, and Perfumes in a country.

13 Product Registration Number: it corresponds to the company identification number and the Resolution or Product Marketing Authorization number.

14 Ingredients/Composition: Qualitative description of formula ingredients by its generic name, using the coding of substances set forth in the International Nomenclature of Cosmetic Ingredients (INCI).

15 Warnings and Use Restrictions: they are those set forth in the list of substances when require the obligation of informing their presence on the label and those established in Annex V of this Resolution "Technical Regulation Regarding General Mandatory Labeling For Personal Hygiene Products, Cosmetics, and Perfumes".

C) GENERAL MANDATORY LABELING

RE.	ITEM	PACKAGING
1	Product name and group/type to which it belongs to if not implicit in the name.	Primary and Secondary
2	Brand	Primary and Secondary
3	Product registration number	Secondary
4	Batch or Departure	Primary
5	Shelf Life	Secondary
6	Content	Secondary
7	Country of origin	Secondary
8	Manufacturer/Importer/Holder	Secondary
9	Manufacturer/Importer/Holder Head Office	Secondary
10	Use instructions (if needed)	Primary or Secondary
11	Warnings and Use Restrictions (if needed)	Primary and Secondary
12	Specific Labeling	Primary and Secondary
13	Ingredients/Composition	Secondary

D) REMARKS

1 - When there is no secondary packaging, all required information should be in the primary packaging.

2 - The Use Instructions may be in an attached leaflet. In this case, it should be indicated in the primary packaging: - "See attached leaflet".

3 - When the packaging is small and it is not possible to include warning and use restrictions, they may be in an attached leaflet. It should be indicated in the primary packaging: - "See attached leaflet".

ANNEX VI

TECHNICAL REGULATION REGARDING SPECIFIC LABELING FOR PERSONAL HYGIENE PRODUCTS, COSMETICS, AND PERFUMES

a) AEROSOLS

- 1 Flammable. Do not pulverize near fire;
- 2 Do not drill, or set it on fire;
- 3 Do not expose to sun or temperatures above 50 °C;
- 4 Protect your eyes during application;
- 5 Keep out of reach of children.

b) NEUTRALIZERS, PRODUCTS FOR WAVING, AND SMOOTING HAIR:

- 1 Do not use if scalp is irritated or injured;
- 2 Keep out of reach of children.

c) HAIR BLEACHING AGENTS AND HAIR DYES:

- 1 May cause allergic reaction. Do the touch test (describe);
- 2 Do not use in the eyelashes and eyebrows;
- 3 Do not use if scalp is irritated or injured;
- 4 In case of contact with eyes rinse with plenty of water;
- 5 Keep out of reach of children.

d) HAIR DYES WITH LEAD ACETATE:

- 1 Do not use if scalp is irritated or injured;
- 2 Improper use may cause poisoning by lead absorption;
- 3 Apply only on the scalp (hair);
- 4 After use, wash your hands using plenty of water to avoid accidental ingestion;
- 5 Keep out of reach of children.

e) DEPILATORY AND EPILATORY:

- 1 Do not apply to irritated or injured areas;
- 2 Do not leave applied for longer than indicated in the use instructions;
- 3 Do not use for shaving;
- 4 In case of contact with eyes rinse with plenty of water;
- 5 Keep out of reach of children.

f) TOOTHPASTES AND MOUTH WASHINGS WITH FLUOR:

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

- 2 Indicate the use instructions, if needed;
- 3 Do not use in children younger than 6 years. (Only for mouthwashes).

g) ANTIPERSPIRANTS/ANTIPERSPIRANTS PRODUCTS:

- 1 Use only on indicated areas;
- 2 Do not use if the skin is irritated or injured;
- 3 If irritation and/or itching occurs at the applied area, discontinue use immediately.

h) HAIR TONICS:

- 1 In case of a scalp irritation, discontinue use.

ANNEX VII

Statement of Responsibility
<p>The Company, (<u>company's corporate name</u>), duly authorized by the National Health Surveillance Agency - Anvisa under number (<u>working Authorization number</u>), herein represented by its Technician in Charge and by its Legal Representative, hereby declares the product (<u>product name and brand</u>) fulfills the regulations and other legal devices regarding the process control and finished product and other technical requirements regarding the Good Manufacturing Practices relevant to the product category.</p> <p>The company hereby declares that it has substantive data attesting to the safety and efficiency of the product purpose, and that it does not constitute a health risk when used in compliance with the use instructions and further actions of the product sales package during its shelf life.</p>

The company assumes before Anvisa that the product fulfills the specific technical requirements set forth in legislation in force, as well as the list of substances, the rulings of labeling, and product correct classification.

It hereby declares that the label does not contain therapeutic indications, or denominations and indications inducing error, mistake, or confusion regarding its provenience, origin, composition, purpose, or safety.

It hereby declares to be aware that the regulated product is subject to Auditing, Marketing monitoring and Registration inspection by the proper Sanitary Health Authority and once an irregularity is found, the product will be cancelled, without prejudice to the civil, administrative and criminal liabilities.

The undersigned hereby assume before this Agency that the failure to the provisions set forth in the regulations in force and its updates, constitutes a sanitary infraction, and the transgressors are subject to the penalties provided by Law.

Date	Legal Representative	Technician in Charge
_____	_____	_____

ANNEX VIII

Grade 2 Products subject to Registration

1. Lipstick and Lip gloss for children.
2. Sunblock/anti-sun.
3. Blush/rouge for children.
4. Suntan lotion.
5. Cologne for children.
6. Conditioner for children.
7. Toothpaste for children.
8. Mouth rinsing for children.
9. Hair rinse for children.
10. Nail polisher for children.
11. Hair fixer for children.
12. Wet wipes for children hygiene.
13. Cleaning product for children.
14. Hair dyeing and/or hair straightening products.
15. Skin protection product for children.

16. Sunscreen for children.
17. Sunscreen.
18. Insect repellent.
19. Soap for children.
20. Talc/starch for children.
21. Shampoo Conditioner for children.
22. Shampoo for children.
23. Antiseptic hand gel.