LATINI GROUP
Integrated
Business
Solution

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# BOARD RESOLUTION - RDC No. 752, OF SEPTEMBER 19, 2022

**(Published in DOU No. 180 of September 21, 2022)**

It provides for the definition, classification , technical requirements for labeling and packaging, parameters for microbiological control, as well as technical requirements and procedures for the regularization of personal care products, cosmetics and perfumes.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the attributions conferred on it by article 15, III and IV, together with article 7, III and IV of Law No. 9,782, of January 26, 1999, and article 187, VI, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution, as resolved at a meeting held on September 14, 2022, and I, the Chief Executive Officer, determine its publication.

## CHAPTER I INITIAL PROVISIONS

### SECTION I

### GOAL

Art. 1 This Resolution establishes the definition, classification, technical requirements for labeling and packaging, parameters for microbiological control, as well as technical requirements and procedures for the regularization of personal care products, cosmetics and perfumes.

Art. 2 This Resolution incorporates into the National Legal System the GMC MERCOSUR Resolutions No. 110/1994 "Definition of Cosmetic Products", 48/2021 "Mercosur Technical Regulation on Labeling for Personal Care Products, Cosmetics and Perfumes", 07/2005 "Classification of Personal Care Products, Cosmetics and Perfumes", 44/2018 "Technical Requirements for Personal Care Products, Cosmetics and Perfumes" and 51/1998 "Parameters for Microbiological Control of Personal Care Products, Cosmetics and Perfumes".

### SECTION II

### DEFINITIONS

Art. 3 For the purpose of this Resolution, the following definitions are adopted:

1 - warnings and restrictions of use: warnings and restrictions established in the lists of substances mentioned in article 6 of this Resolution, when they require the obligation to inform their presence on the label, and those established for the specific label of some products, without prejudice to others determined by the manufacturer, including the

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appropriate conditions for storage, when necessary;

2 - prior communication: it is the administrative procedure to be applied to inform Anvisa of the intention to commercialize a product exempt from registration by means of notification;

3 - primary packaging: wrap or container that is in direct contact with the products;

4 - secondary packaging: packaging intended to contain the primary packaging or primary packaging;

5 - manufacturer: company that has the necessary facilities for the manufacture of personal care products, cosmetics and perfumes, authorized before the competent health authority;

6 - instruction leaflet: printed text accompanying the product, containing additional information;

7 - group: includes the type of cosmetic formulation (e.g. shampoo, soap, lipstick, cream) and the purpose of the product, if not implicit in the type of formulation;

8 - importer: company that is responsible for the importation of personal care products, cosmetics and perfumes, authorized before the competent health authority;

9 ingredients or composition: qualitative description of the components of the formula through their generic name, using the coding of substances established by the International Nomenclature of Cosmetic Ingredients (INCI);

10 - batch or start: quantity of a product produced in a manufacturing cycle, duly identified, whose main characteristic is homogeneity;

11 - trademark: element that identifies one or more products of the same company or manufacturer and that distinguishes them from products of other companies or manufacturers, according to the legislation of industrial property;

12 - mode of use: set of instructions for the correct application of the product.

13 - name: designation of the product to distinguish it from others, although

14 - country of origin: country of production or industrialization of the product;

15 - shelf life: time in which the product maintains its properties, provided that it is kept in the original packaging and without damage, in appropriate conditions of storage and use;

16 - personal hygiene products, cosmetics and perfumes: are preparations consisting of natural or synthetic substances, for external use in the various parts of the human body, skin, capillary system, nails, lips, external genital organs, teeth and mucous membranes of the oral cavity, with the exclusive or main purpose of cleaning, perfume them, alter their appearance and or correct body odors and or protect them or keep them in good condition;

17 - Grade 1 products: are personal care products, cosmetics and perfumes whose formulation complies with the definition adopted in item XVI of this article and which are characterized by having basic or elementary properties, whose proof is not initially necessary and do not require detailed information as to their way of using and their restrictions of use, due to the intrinsic characteristics of the product, as mentioned in the indicative list "LIST OF GRADE 1 PRODUCT GROUPS" set out in item "I" of Annex I;

18 - Grade 2 products: are personal care products, cosmetics and perfumes whose formulation complies with the definition adopted in item XVI of this article and which have specific indications, whose characteristics require proof of safety and / or efficacy, as well

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as information and care, mode and restrictions of use, as mentioned in the indicative list "LIST OF GROUPS OF PRODUCTS OF GRADE 2" established in item "II" of Annex I;

19 - tester or tester: regularized demonstration product exposed at the point of sale, close to its respective product of sale, with the sole purpose of experimentation of use by the consumer;

20 - label or labelling: printed or lithographed identification, as well as painted or engraved words, pressure decal or other techniques, applied directly on containers, packaging, wrappings, wraps or any other packaging protector; and

21 - holder of the regularization of the product: is the legal entity responsible for the regularization of the product, in accordance with this Resolution, before the competent sanitary authority, on which falls the administrative, civil and criminal liability.

## CHAPTER II

## GENERAL PROVISIONS

Art. 4 The products for the purpose of ambient odorants are classified as personal care products, cosmetics and perfume Grade 1.

Art. 5 The holder of the regularization of the product must:

1. - have supporting data attesting to the quality, safety and efficacy of its products and the suitability of the respective labeling statements, as well as the technical requirements established in the Arts. 8th and 9th of this Resolution, which must be presented to the health surveillance bodies, whenever requested or during inspections;

2. - ensure that the product does not constitute a health risk when used in accordance with the instructions for use and other measures contained in the sales packaging of the product during its period of validity; and

3. - attach to the transaction the Term of Responsibility, duly signed by the Technical Responsible and Legal Representative of the company, as Annex II.

Art. 6 For the purpose of this Resolution, personal care products, cosmetics and perfumes must comply with the provisions of:

list of active ingredients allowed in cosmetic products to straighten or curl hair - Normative Instruction - IN No. 124, of March 24, 2022, published in DOU No. 61, of March 30, 2022, Section 1, Page 295, and its updates;

List of ultraviolet filters allowed for personal care products, cosmetics and perfumes - Collegiate Board Resolution - RDC No. 600, of February 9, 2022, published in DOU No. 33, of February 16, 2022, Section 1, p. 136, and its updates;

- List of permitted coloring substances for personal care products, cosmetics and perfumes - Collegiate Board Resolution - RDC No. 628, dated March 10, 2022, published in DOU No. 51, dated March 16, 2022, Section 1, p. 123, and its updates;

4. list of substances of preservative action allowed for personal care products, cosmetics and perfumes - Collegiate Board Resolution - RDC No. 528, of August 4, 2021, published in DOU No. 151, of August 11, 2021, Section 1, p. 96, and its updates;

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5. list of substances that may not be used in personal care products, cosmetics and perfumes - Collegiate Board Resolution - RDC No. 529, of August 4, 2021, published in DOU No. 151, of August 11, 2021, Section 1, p. 101, and its updates; and

6. - list of substances that personal care products, cosmetics and perfumes should not contain except under the conditions and with the restrictions established - Collegiate Board Resolution - RDC No. 530, of August 4, 2021, published in DOU No. 151, of August 11, 2021, Section 1, p. 119 and Collegiate Board Resolution - RDC No. 645, dated March 24, 2022, published in DOU No. 30, March 2022, Section 1, p. 309, and its updates.

Art. 7 For the purpose of this Resolution, personal care products, cosmetics and perfumes, classified as Grade 1, must adopt the provisions of this Resolution and the following criteria:

1 - not contain substances from the Restrictive List, contained in the Collegiate Board Resolution - RDC No. 530, of 2021, Collegiate Board Resolution - RDC No. 645, of 2022, and its updates, which are specific to products classified as Grade 2, except in cases where the presence of the substance in the formulation does not change the purpose of the product and does not mischaracterize its classification as Grade 1; and;

2 - not contain substances from the List of Ultraviolet Filters for the protection of the skin against the harmful effects of the sun's rays, contained in the Collegiate Board Resolution - RDC No. 600, of 2022, and its updates, since the presence of these substances characterizes Grade 2 product.

## CHAPTER III

## TECHNICAL REQUIREMENTS

Art. 8 The product regularization process must be instructed with the following information:

1. bibliography and/or reference of ingredients;
2. copy of the original formula of the imported product;
3. microbiological specifications of the finished product;
4. organoleptic and physico-chemical technical specifications of the product finished ;
5. purpose of the product;
6. qualitative-quantitative formula;
7. function of the ingredients of the formula.

VIII - labeling art project;

IX - Summary of data proving the effectiveness of the benefits attributed the product, where the nature of the benefits justifies and where it appears on the label.

- Summary of the data proving safety of use, only when the proof of specific safety is required by current legislation or when some safety attribute is expressed on the label; and summary of stability data.

- § 1 - The information referred to in item I of the caput of this article must include identification, safety and efficacy data, when the substance does not appear in the INCI nomenclature.
- § 2 - The information referred to in item III of the caput of this article follows the microbiological parameters provided for in Chapter V of this Resolution.
- § 3 - The information referred to in item IV of the caput of this article must indicate a range

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of acceptance for the determination of substances or group of main functional substances in products of the categories insect repellent, sunscreen, hair straightener and hair curl.

- § 4 - The information referred to in item V of the caput of this article must be presented when it is not implied in the name of the product.
- § 5 - The information referred to in item VI of the caput of this article must be presented with all the components of the formula specified by the INCI denominations and the quantity of each component expressed as a percentage w / p (weight by weight) by means of the decimal metric system.
- § 6 - The information referred to in item VII of the caput of this article must be cited for each component in the formula.
- § 7 - The information referred to in item VIII of the caput of this article shall present the data and warnings provided for in Chapter IV of this Resolution.
- § 8 - The abstracts referred to in items IX and X of the caput of this article must contain, at least, objective, methodology, results and conclusion.
- § 9 - The summary referred to in item XI of the caput of this article must contain, at least, methodology and conclusion that support the declared validity period.
- § 10. The information referred to in item XI of the caput of this article must include the determination of the main substances or groups of functional substances in the case of insect repellents, sunscreens, hair straighteners and hair curls.
- Art. 9 In addition to the information referred to in article 8 of this Resolution, the company must also keep under its custody and at the disposal of the health authority:

1 - authorization of operation or qualification of the original company;

2 full evidence of the effectiveness of the benefits attributed to the product, where justified by the nature of the benefit and where it appears on the label;

3 complete data proving safety of use, only when proof of specific safety is required by current legislation or when some safety attribute is expressed on the label;

4 complete stability data;

5 microbiological specifications of raw materials, where applicable; VI - technical specifications of the packaging material;

VII - organopletic and pysicho-chemical technical specifications of materials raw
- manufacturing process; and
- batch coding system

§ 1 - The information referred to in item I of the caput of this article must be from the domestic or importer manufacturer for imported products.

§ 2 - The information referred to in item IV of the caput of this article shall include the determination of the main substances or groups of functional substances in the case of insect repellents, sunscreens, hair straighteners and hair curls.

§ 3 The information referred to in item VIII of the caput of this article must follow the Good Manufacturing and Control Practices provided for in the Collegiate Board Resolution
- RDC No. 48, dated October 25, 2013, and its updates.

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§ 4 - The information referred to in item IX of the caput of this article must contain guidance to interpret the coding system.

Art. 10. It is not mandatory to present the certificate of free sale (CVL) consularized or apostilled in the process of regularization of the product, nor to keep it under the custody of the company.

## CHAPTER IV

## LABELLING AND PACKAGING

### SECTION I

### GENERAL LABELLING

Art. 11. The labelling shall be legible, clear, truthful and sufficient to prevent improper use or use which does not correspond to the purposes of use laid down for personal care products, cosmetics and perfumes.

Art. 12. The labeling must not contain trade names, trademarks, images, electronic links or sayings that:

1. - induce error, deception or confusion as to their properties, origin or nature, origin, composition, purpose of permissible use or safety;

2. - represent therapeutic claims attributed to the use of the product or its ingredients, such as, for example, prevention or treatment of bruises, wounds, cracks, pains, inflammations, cramps, varicose veins, pediculosis, including action of elimination, reduction, death or tipping of lice and nits or complete protection against them;

3. - refer to the action of elimination, reduction, death or tipping of insects or complete protection against them; or

4. - mention the disinfectant property or refer to the complete elimination of micro-organisms.

Art. 13. The following data shall appear on the labelling, including tasters/testers:

1 - of the primary packaging:

2 - warnings and restrictions on use (if any);

3 - the group to which it belongs if it is not implied in the name;

4 - lot or start;

5 - brand; and

6 - product name.

7 - secondary packaging:

8 - warnings and restrictions on use (if any)

9 - content;

10 customer service data (telephone, e-mail, website or other means);

11 the group to which it belongs if it is not implied in the name;

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12 number of the product regularization process;

13 number of the Company Operating Authorization (AFE) of the holder, referring to the class (personal hygiene product, cosmetic and / or perfume);

14 number of the National Registry of Legal Entities (CNPJ) of the holder;

15 name (corporate name) of the holder;

16 ingredients or composition (using INCI substance coding);

17 product name;

18 brand;

19 country of origin; and

20 shelf life.

21 the primary packaging or the secondary packaging:

a) mode of use (if applicable).

Art. 14. All the information referred to in items II and III of article 13 of this Resolution must appear on the primary packaging, when there is no secondary packaging.

Art. 15. When the primary packaging is small or does not allow the inclusion of the mode of use and the warnings and/or restrictions of use, this information may be included in a leaflet, attached material or in the inner part of the secondary packaging.

Single paragraph. In the case referred to in the caput of this article, the phrase "See leaflet/attached material/inner part of the secondary packaging" shall appear on the packaging(s), preceded by the description of the information, such as: "Method of use: See leaflet"; "Warnings: See inside the secondary packaging".

Art. 16. If the product contains primary and secondary packaging, and the primary packaging is small or does not allow the inclusion of warnings and / or restrictions of use, it is allowed to replace this information by the description "Warnings and restrictions of use: see outer packaging".

Art. 17. An additional transparent wrap or box is considered exempt from the obligations set forth in art. 13 of this Resolution, provided that it allows the clear visualization of the mandatory labeling arranged on the primary or secondary packaging of the product and does not alter or add technical information about the requirements established in this Resolution.

Art. 18. If the product has primary and secondary packaging and the primary packaging does not accompany the product during use, as with solid soaps, all mandatory information must be included in the secondary packaging, and the primary packaging does not require information.

Art. 19. In the case of a product kit, the shelf life to be inserted in the secondary packaging should be that of the product with the shortest remaining shelf life.

Art. 20. The mandatory information entered in labeling must be legible in the Portuguese language in Brazil, except for the cosmetic ingredient identification code (INCI), name and trademarks.

Single paragraph. The composition of the product must also be described in Portuguese of Brazil pursuant to Collegiate Board Resolution - RDC No. 646, March 24, 2022, and its updates.

Art. 21. For imported products whose original labels do not contain the information required by the importing country, suitability is accepted by means of a label or other means containing the

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missing information.

§ 1 - The information mentioned in the caput of this article may not be presented in digital format and may be placed both at the origin and at the destination.

§ 2 - If the information mentioned in the caput of this article is placed at the destination, the adaptation must be made before its commercialization.

Art. 22. Imported products may not claim therapeutic action, nor contain prohibited or unproven sayings regardless of the language in which the label is written.

Single paragraph. If necessary, the label should be covered in whole or in part with an additional label before it is marketed.

Art. 23. The labeling of the products that are tasters or testers exposed only in their primary packaging must present at least the mandatory information on the primary packaging, according to item I of article 13 of this Resolution, the validity period and the phrase "Prohibited Sale".

## SECTION II

## SPECIFIC LABELLING

Art. 24. The following personal care products, cosmetics and perfumes must contain on their labelling the warnings and/or restrictions on use indicated the following, or use wording that ensures the same interpretation: I - aerosols:

1. "Avoid direct inhalation of this product";
2. Indicate the minimum distance of application;
3. "Flammable. Do not spray near the fire";
4. "Keep out of reach of children";
5. "Do not drill or incinerate";
6. "Do not expose to the sun or to temperatures exceeding 50 °C"; and
7. "Protect the eyes during application".
8. hair bleaching agents and hair dyes
9. "CAREFUL. It can cause skin irritation or allergic reaction. Before use, do the touch test" (describe);
10. "In case of contact with the eyes, wash with plenty of water";
11. "Keep out of reach of children";
12. "Do not apply if the scalp is irritated or injured"; and
13. "Do not use on eyelashes.
14. Body hair bleaching agents:
15. "In case of skin irritation, wash it thoroughly with water and avoid exposure to the sun";
16. "Do not apply the product and be exposed to the sun simultaneously";
17. "Do not apply if the skin is irritated or injured";
18. "Do not use on eyelashes and pubic hair"; and

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19. "Obey the time of contact of the product with the skin. Then wash the area abundantly with water."

20. - Tan activators/accelerators:

21. a) "This product is not a sunscreen".

22. - Simulatory self-tanners/tanners:

23. a) "Attention: does not protect against solar action".

24. - fluoride toothpastes and mouthwashes:

25. Indicate the mode of use, when necessary;

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

27. "Do not use on children under 6 years" (only for mouthwashes uccal)

28. depilatories and epilatories:

29. ‘’In case of contact with eyes, wash with plenty of water’’ (except for depilatory waxes).

30. "Keep out of reach of children";

31. "Do not apply to irritated or injured areas";

32. "Do not leave applied for longer than indicated in the instructions of use

33. "Do not use for the purpose of shaving" (except for depilatory waxes).

34. - neutralizers, products to curl and straighten hair:

35. - "This preparation should only be used for the purpose for which it is intended, being DANGEROUS its use for any other purpose or area of application";

36. - "Keep out of reach of children"; and

37. - "Do not apply if the scalp is irritated or injured." IX

38. - antiperspirant products:

39. - "If irritation and/or itching occurs at the application site, discontinue the use immediately";

40. - "Do not use if the skin is irritated or injured"; and

41. - "Use only in the indicated areas."

42. - Oral hygiene products suitable for sensitive teeth:

43. - "Avoid ingestion of the product"; and

44. - "Persisting tooth sensitivity for more than 4 weeks, discontinue use of the product and consult your dentist."

45. hypoallergenic products:

a) "This product has been formulated in such a way as to minimize possible emergence of alllergy”.

b) products for intimate hygiene:

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1. "Apply only to the external genital organs"; and

2. "Overuse of the product can be a source of genital irritation." XIII - tincture for body hair:

36. "CAREFUL. It can cause skin irritation or allergic reaction. Before use do the touch test'' (describe)

2. "In case of contact with the eyes, wash with plenty of water";

3. "In case of skin irritation, wash it thoroughly with water and avoid exposure to the sun";

4. "Keep out of reach of children";

5. "Do not apply if the skin is irritated or injured";

6. "Do not use on eyelashes and pubic hair"; and

7. "Obey the time of contact of the product with the skin. Then wash the area abundantly with water."

XIV - hair tonics/lotions:

a) "In case of irritation of the scalp, discontinue use".

## SECTION III

## PACKAGING

Art. 25. Packaging in the form of aerosols for talc.

Art. 26. containers of products presented in the form of an aerosol,
Being glass surrounded by plastic material, they must contain small holes for the exit of the contents, if it breaks.

Art. 27. The containers of products in the form of aerosol presses may not have a capacity exceeding 500 (five hundred) milliliters.

## CHAPTER V

## MICROBIOLOGICAL PARAMETERS

Art. 28. The data and technical justifications presented for care of item III of article 8 of this Resolution will be evaluated by Anvisa.

Art. 29. The parameters for microbiological control of personal care products, cosmetics and perfumes are classified into:

I - Type I:

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1. products for children's use;

2. products for the eye area; and

3. products that come into contact with mucous membranes. II - Type II:

a) other cosmetic products susceptible to microbiological contamination.

Art. 30. The parameters for microbiological control of personal care products, cosmetics and perfumes classified as "Type I" are as follows:

1. - count of aerobic total mesophilic microorganisms: no more than $10^2$ CFU/g or ml, the maximum limit being 5 x $10^2$ CFU/g or ml;

2. - absence of Pseudomonas aeruginosa in 1g or 1ml; III

- absence of Staphylococcus aureus in 1g or 1ml;

IV - absence of total and fecal coliforms in 1g or 1ml; and

V - absence of reducing Clostridia sulfite in 1g (exclusively for talcos):

Art. 31. The parameters for microbiological control of hygienic products cosmetics and and perfumes classified as ‘’Type II’’ as follows:

- count of aerobic total mesophilic microorganisms: not more than $10^3$ CFU/g or ml, the maximum limit being equal to 5 x $10^3$ CFU/g or ml;
- absence of Pseudomonas aeruginosa in 1g or 1ml; III - absence of Staphylococcus aureus in 1g or 1ml;
- absence of total and fecal coliforms in 1g or 1ml; and

Absence of reducing Clostridia sulfite in 1g (exclusively for talc)

## CHAPTER V

## PROCEDURES FOR PRODUCT REGULARIZATION

### SECTION I

### GENERAL PROCUDURES

Art. 32. The regularization of personal care products, cosmetics and perfumes is carried out trough and electronic procedure trough the Anvisa portal.

§ 1 - The publicity of the regularization of products exempt from registration is ensured through disclosure on the Anvisa portal, at which time the commercialization of these products is allowed.

§ 2 - The publicity of the regularization of products subject to registration is ensured through publication in the Official Gazette, at which time the commercialization of these products is allowed.

§ 3 - The guidelines necessary for the electronic procedure for the regularization of products are available on the Anvisa portal.

Art. 33. The documents generated at the end of the electronic procedure must be kept in the

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company.

Single paragraph. The term of responsibility must be signed by the Technical Responsible and the Legal Representative of the company, complementing all the documentation related to the product.

Art. 34. Products in the following groups are subject to the procedure Registration:

– Tanning:
- antiseptic gel for hands;
- product to straighten the hair;
- product to straighten and dye the hair;
- product to curl the hair;
- sunscreen;
- children's sunscreen;
- insect repellent; and
- infant insect repellent.

Art. 35. The products of the groups that are not listed in article 34 of this Resolution are exempt from registration and are subject to the procedure of prior communication to Anvisa.

Art. 36. The need to submit innovative products, not yet regulated, to the registration procedure will be established in its own regulation.

Art. 37. The companies that own and/or manufacture national products must have a Company Operating Authorization at Anvisa to manufacture the class of products (personal hygiene product, cosmetics and/or perfume) that they wish to regularize and/or manufacture and must have a License with the competent Sanitary Authority.

Art. 38. Companies that own and/or import imported products must have a Company Operating Authorization at Anvisa to import the class of products (personal hygiene product, cosmetics and/or perfume) that they wish to regularize and/or import and must have a License with the competent Sanitary Authority.

Art. 39. Compliance with Good Manufacturing Practices will be verified in the producing and/or importing establishment through an inspection carried out by the competent Sanitary Authority.

## SECTION II

## VALIDITY AND REGULARIZATION

Art. 40. The registration is valid for 10 (ten) years, counted from the day of its publication in the Official Gazette of the Union, and may be revalidated successively for the same period.

§ 1 - The revalidation of the product regularization process must be required in the first half of the last year of the decade of validity.

§ 2 - The expiry of the process whose revalidation has not been requested within the period referred to in paragraph 1 of this article shall be declared.

Art. 41. Products exempt from registration are exempt from revalidation.
§ 1 - The maintenance of the regularization of the products referred to in the caput is linked to compliance with the technical requirements of this Resolution, the specific regulations and the declaration of interest in the continuity of the commercialization of the products every 10 (ten) years, counted from the day of notification of the product in Anvisa.

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§ 2 - The interest in the continuity of the commercialization of the products must be declared, by means of a specific form in the electronic petitioning system, in the last six months of the decade of regularization.

§ 3 - The regularization process of the product whose declaration of interest in the continuity of the commercialization has not been carried out within the period referred to in § 2 of this article shall be canceled.

Art. 42. The holder of the regularization of the product that intends to no longer commercialize it in the Brazilian market must request the cancellation of its regularization to Anvisa.

## CHAPTER VII

## FINAL AND TRANSITIONAL PROVISIONS

Art. 43. Anvisa may establish other forms of petitioning, including in non-electronic format, according to the interest of the Public Administration.

Art. 44. The provisions of this Resolution do not exclude the observance of other regulations provided for in the sanitary legislation, pertinent to personal hygiene products, cosmetics and perfumes.

Art. 45. Failure to comply with the provisions of this Resolution or other regulations related to personal hygiene products, cosmetics and perfumes results in the cancellation of the regularization and its disclosure on the Anvisa website, without prejudice to other actions or measures provided for in the legislation in force.

Art. 46. The authenticity and veracity of the information provided to Anvisa are the responsibility of the holder of the regularization of the product, and any irregularity detected by ANVISA, contrary to the provisions of the relevant sanitary legislation, constitutes a sanitary infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liabilities.

Art. 47. The deadline is set until October 3, 2025 for the adequacy of the labeling, under the terms of Chapter IV, for products already regularized in Anvisa until the date of entry into force of this Resolution.

Single paragraph. Products manufactured in accordance with the legislation in force at the time of regularization, before the adequacy of the labeling and within the period established by the caput of this article, may be marketed until the end of their expiration dates.

Art. 48. Processes that do not have the appropriate labelling within the period established in the caput of article 47 will be cancelled.

Single paragraph. Processes that are with a petition for change of labeling pending analysis will not be canceled, provided that they are filed within the period established in the caput of article 47.

Art. 49 Petitions for registration or labeling changes filed before the effective date of this Resolution, or which are already under analysis at Anvisa, shall be analyzed in accordance with the Resolutions in force at the time of the protocol.

Art. 50. The following are hereby repealed:

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I - the Resolution of the Collegiate Board of Directors - RDC No. 13, of January 17, 2003; II - the Resolution of the Collegiate Board of Directors - RDC No. 7, of February 10, 2015, published in DOU No. 29, dated February 11, 2015, Section 1, p. 39;

1. - Article 9 of the Collegiate Board Resolution - RDC No. 237, of July 16, 2018, published in DOU No. 136, of July 17, 2018, Section 1, p. 70;

2. - the Collegiate Board Resolution - RDC No. 288, of June 4, 2019, published in DOU No. 107, of June 5, 2019, Section 1, p. 49;

3.- the Collegiate Board Resolution - RDC No. 312, of October 10, 2019, published in DOU No. 201, of October 16, 2019, Section 1, p. 105; and

4. - the Collegiate Board Resolution - RDC No. 630, dated March 10, 2022, published, in DOU No. 51, dated March 16, 2022, Section 1, p. 126.

Art. 51. This Resolution enters into force on October 3, 2022.

**ANTONIO BARRA TORRES**
**CHIEF EXECUTIVE OFFICE**

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## ATTACHEMENT I

### CLASSIFICATION OF PERSONAL CARE PRODUCTS, COSMETICS AND PERFUMES

1. The criteria for this classification were defined according to the probability of occurrence of unwanted effects due to the inappropriate use of the product, its formulation, purpose of use, areas of the body to which they are intended and care to be observed when using them.

2. The exceptions mentioned in item LIST OF GRADE 1 PRODUCT GROUPS characterize Grade 2 products.

### LIST OF GRADE 1 PRODUCT GROUPS

1. Cologne, Perfumed Water, Perfume and Aromatic Extract.
2. Cuticle softener (non-caustic).
3. Oral flavoring.
4. Facial/body base (without photoprotective purpose).
5. Lipstick and lip gloss (no photoprotective purpose).
6. Blush/Rouge (no photoprotective purpose)
7. Conditioner/Cream rinse/Capillary rinse (except those with anti-fall, anti-dandruff and/or other specific benefits that warrant prior proof).
8. Facial concealer (no photoprotective purpose).
9. Cream, lotion and gel for the face (without photoprotective action of the skin and for the exclusive purpose of hydration).
10. Mechanical, body and/or exfoliating cream, lotion, gel and exfoliating oil ("peeling") facial.
11. Hand cream, lotion, gel and oil (no photoprotective action, no indication of individual protective action for work, such as personal protective equipment - PPE - and for the exclusive purpose of hydration and / or refreshment).
12. Cream, lotion, gel and oils for the legs (for the sole purpose of hydration and / or refreshment).
13. Cream, lotion, gel and oil for facial cleansing (except for acneic skin).
14. Cream, lotion, gel and oil for the body (except those with specific purpose of anti-stretch mark action, or anti-cellulite, without photoprotective action of the skin and with exclusive purpose of hydration and / or refreshment).
15. Cream, lotion, gel and foot oil (for the sole purpose of hydration and/or refreshment).
16. Eyeliner for lips, eyes and eyebrows.
17. Makeup remover.
18. Toothpaste (except those with fluoride, those with anti-plaque, anticaries, anti-tartar action, with indication for sensitive teeth and chemical whiteners).

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19. Mechanical/epilatory/epilatory depilatory.

20. Axillary deodorant (except those with antiperspirant action).

21. Deodorant cologne.

22. Body deodorant (except intimate deodorant).

23. Pedic deodorant (except those with antiperspirant action).

24. Flavoring mouthwash (except those with fluoride, antiseptic and antiplaque action).

25. Enamel, varnish, shine for nails.

26. Tapes for mechanical removal of impurity from the skin.

27. Nail strengthener.

28. Kajal.

29. Pencils for lips, eyes and eyebrows.

30. Wet wipes (except those with antiseptic action and / or other specific benefits that justify prior proof).

31. Facial tonic lotion (except for acneic skin).

32. Mascara for eyelashes.

33. Body mask (for the sole purpose of cleansing and/or moisturizing).

34. Face mask (except for acneic skin, chemical peel and / or other specific benefits that justify prior proof).

35. Shaper/fixer for eyeshadows.

36. Neutralizing for permanent and smoothing.

37. Facial powder (without photoprotective purpose).

38. Bath/immersion products: salts, oils, softgels and bath of foam

39. Shaving products (except those with antiseptic action).

40. Products to fix, model and / or beautify the hair: fasteners, lacquers, tip repairers, hair oil, shiners, mousses, creams and gels to model and settle the hair, hair restorer, hair mask and hair humidifier.

41. Products for pre-shaving (except those with antiseptic action).

42. Post-shaving products (except those with antiseptic action).

43. Lip balm without sunscreen.

44. Nail polish remover.

45. Abrasive soap /mechanical exfoliant (except those with antiseptic action or chemical exfoliant).

46. Facial and/or body soap (except those with antiseptic action or chemical exfoliating).

47. Deodorant soap (except those with antiseptic action).

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48. Enamel dryer.

49. Eyelid shade.

50. Talc/powder (except those with antiseptic action).

51. Shampoo (except those with anti-fall, anti-dandruff and/or other specific benefits that justify prior proof).

52. Conditioner shampoo (except those with anti-fall, anti-dandruff and/or other specific benefits that justify prior proof).

**LIST OF GRADE 2 PRODUCT GROUPS**

1. Hydrogen peroxide 10 to 40 volumes (including creamy except medicinal products).

2. Axillary antiperspirant.

3. Pedic antiperspirant.

4. Tan activator/accelerator.

5. Lip lipstick and infant lip gloss.

6. Blush/ children's rouge.

7. Tanning.

8. Simulatory bronzer.

9. Skin lightener.

10. Chemical nail whitener.

11. Whitener for hair and body hair.

12. Children's colony.

13. Anti-dandruff/anti-fall conditioner.

14. Children's conditioner.

15. Anti-caries toothpaste.

16. Anti-plaque toothpaste.

17. Anti-tartar toothpaste.

18. Toothpaste whitener/chemical tooth whitener.

19. Toothpaste for sensitive teeth.

20. Infant toothpaste.

21. Chemical depilatory.

22. Hair bleach.

23. Axillary antiperspirant deodorant.

24. Pedic antiperspirant deodorant.

25. Deodorant for intimate use.

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26. Anti-plaque mouthwash.
27. Antiseptic mouthwash.
28. Infant mouthwash.
29. Anti-dandruff/anti-stay capillary enxaguatório.
30. Infant hair rinse.
31. Coloring / toning hair rinse.
32. Chemical peeling exfoliator.
33. Enamel for children's nails.
34. Children's hair fixer.
35. Wet wipes for child hygiene.
36. Makeup with photoprotector.
37. Children's cleaning / sanitizing product.
38. Product to straighten and / or dye the hair.
39. Product for eye area (except those of makeup and / or moisturizing and / or makeup remover).
40. Product to avoid nail biting.
41. Product to curl the hair.
42. Product for acneic skin.
43. Product for wrinkles.
44. Protective product for children's skin.
45. Lip balm with photoprotector.
46. Sunscreen.
47. Children's sunscreen.
48. Cuticle remover.
49. Chemical nicotine stain remover.
50. Insect repellent.
51. Antiseptic soap.
52. Children's soap.
53. Soap for intimate use.
54. Talc/infant starch.
55. Talc/antiseptic powder.
56. Temporary/progressive/permanent hair dye.
57. Hair Tonic/Lotion.
58. Anti-dandruff/anti-fall shampoo.

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59. Coloring shampoo.
60. Anti-dandruff/anti-fall conditioner shampoo.
61. Children's conditioner shampoo.
62. Children's shampoo.

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**ATTACHEMENT II**

| **STATEMENT OF RESPONSABILITY** |
|---|
| The company (describe the corporate name of the company), duly authorized by the National Health Surveillance Agency - Anvisa under the number (describe the number of operating authorization), in this act represented by its Technical Responsible and its Legal Representative, declares that the product (describe the name of the product and brand) meets the regulations and other legal provisions regarding the control of process and finished product and other technical parameters related to the Good Manufacturing Practices pertinent to the product category.<br>The company declares that it has supporting data that attest to the safety and efficacy of the proposed purpose of the product and that it does not constitute a risk to health when used in accordance with the instructions for use and other measures contained in the sales packaging of the product during its period of validity.<br>The company assumes before Anvisa that the product meets the specific technical requirements established in the current legislation, as well as the lists of substances, the labeling standards and the correct classification of the product.<br>declares that the labelling does not contain therapeutic indications and particulars, nor names and indications which mislead, deceive or confuse as to their origin, origin, composition, purpose or safety.<br>declares to be aware that the regularized product is subject to audit, market monitoring and inspection of the registration by the competent sanitary authority and, if irregularity is found, the product will be canceled, without prejudice to the applicable civil, administrative and criminal liabilities.<br>The undersigned assume, before this body, that failure to comply with the provisions of current legislation and its updates constitutes a health infraction, and violators are subject to the penalties provided for in the Law. |