

**RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS –  
RDC No. 639, OF MARCH 24, 2022**

It provides for the technical requirements for the regularization of personal care products, cosmetics and children's perfumes.

The Collegiate Board of the National Health Surveillance Agency, in the use of the competences that confer on it the arts. 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of article 187, item VI and §§ 1 and 3, of the Internal Regulations, approved by the Resolution of Collegiate Board of Directors – RDC No. 585, of December 10, 2021, decides to adopt the following Resolution of Collegiate Board of Directors - RDC, as resolved at a meeting held on March 23, 2022, and I, the Chief Executive Officer, determine its publication:

**CHAPTER I  
GENERAL PROVISIONS**

Art. 1 This Resolution establishes the technical requirements regarding the formulation, safety and labeling for regularization of personal hygiene products, cosmetics and children's perfumes, in this regulation designated "children's products".

Art. 2 This Resolution applies to all products intended for children.

Single paragraph. Children between 0 (zero) and 12 (twelve) incomplete years are considered children.

Art. 3 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. 4 The categories and groups provided for children are described in Annex I of this Resolution.

Single paragraph. For the purposes of sanitary regularization, new categories may be evaluated and regularized, provided that the safety is proven and the pertinence of use in children is justified.

Art. 5 The specific requirements for children's products are described in Annex II of this Resolution.

Article 6 The products provided for in Annex I of this Resolution, indicated concomitantly to children and adults, must meet the specific requirements for children's products established in Annex II of this Resolution.

Art. 7 In addition to meeting the requirements of this Resolution, sunscreens intended for children must meet the Collegiate Board Resolution - RDC No. 629, of March 10, 2022, and its updates, and insect repellents must meet the Collegiate Board Resolution - RDC No. 19, of April 10, 2013, and its updates.

Art. 8 The following rules apply to registrations of children's products of categories not provided for in Annex VIII of the Collegiate Board Resolution – RDC No. 7, of 2015, which are in force at the time of entry into force of this Resolution:

1. – the registrations of the products covered by the caput remain with the original validity and their post-registration changes must be carried out by means of secondary petitions in the processes of the current registrations;
2. - the records referred to in the caput are not subject to revalidation, being necessary, after their expiration, a new regularization of the products through the procedures provided for in the Collegiate Board Resolution – RDC No. 7, of 2015 and its updates for products exempt from registration;
3. - the holder of a product covered by the caput who wishes to regularize it as exempt from registration must re-register it as exempts from registration; and
4. – Changes in the registration process are not allowed, from the re-registration of the respective product as exempt from registration.

## **CHAPTER II FORMULATION**

Art. 9 The formulation must, mandatorily, consist of own and safe ingredients for the purpose of proposed use, taking into account the possible cases of accidental ingestion.

Art. 10. The flavorings, flavorings and fragrances or aromatic compositions, eventually, used in the formulation of these products must comply with the Collegiate Board Resolution - RDC No. 530, of August 4, 2021, and its updates, which establishes the criteria for their use.

Art. 11. The microbiological parameters must comply with the Collegiate Board Resolution - RDC No. 630, of March 10, 2022, and its updates, which establishes the "Parameters for Microbiological Control of Personal Care Products, Cosmetics and Perfumes".

Art. 12. The removal of the product should occur easily, such as by simple washing with water, soap, shampoo or other preparations containing surfactants.

Art. 13. In order to avoid the ingestion of the product, the use of ingredients with denaturizing function (bitter taste) is allowed, provided that their use is safe.

Art. 14. Products for adult use: soaps, cleaning and sanitizing products, with antiseptic action, may be extended to children's use, provided that the requirements established in Annex II of this Resolution are met.

§ 1 - Products intended for hand hygiene containing alcohol in their formulation, such as alcohol-gel, may be extended to children's use, provided that they meet the requirements established in Annex II of this Resolution, for product for hygiene / cleaning.

§ 2 - The products referred to in this article may not have children's appeals on their packaging and advertising material.

Art. 15. Deodorants, pedic and axillary, can have antiseptic ingredients in their composition, as long as they are safe.

Single paragraph. Deodorants of the axillary and pedic type cannot contain in their compositions ingredients of action regulating the flow of sweat (antiperspirants).

### **CHAPTER III PACKAGING AND LABELLING**

Art. 16. The labeling statements must meet, in addition to what is established in this Resolution, the other relevant resolutions that establish requirements on mandatory labeling and specific labeling for personal care products, cosmetics and perfumes.

Art. 17. The packaging of the product shall be free of blunt parts, parts that can be easily detached from the packaging and swallowed and toxic constituents.

Art. 18. Children's products may not be presented in aerosol form.

### **CHAPTER IV FINAL PROVISIONS**

Art. 19. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liability.

Art. 20. The following shall be repealed:

- 1.- art. 1 to art. 8 of the Collegiate Board Resolution - RDC No. 237, of July 16, 2018;
- 2.- art. 10 of the Collegiate Board Resolution - RDC No. 237, of July 16, 2018; and

I- Collegiate Board Resolution No. 15, of April 24, 2015. Art. 21. This Resolution enters into force on May 2, 2022.

**ANTONIO BARRA TORRES**