NORMATIVE INSTRUCTION No. 394 OF 15 AUGUST 2025

Provides for general requirements, analytical tolerances, label flow, list of categories, and proof of expiration date for sanitizing products, in accordance with Collegiate Board Resolution No. 989 of 15 August 2025.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VII, Paragraph 1 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Normative Instruction, as decided upon in a meeting held on 13 August 2025, and I, Acting Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This Normative Instruction establishes general requirements, analytical tolerances, label flow, list of categories, and proof of the expiration date for sanitizing products, in accordance with Collegiate Board Resolution No. 989 of 15 August 2025.

Section II

Scope

Article 2. This Normative Instruction applies to all sanitizing products, according to their risk classification.

CHAPTER II

GENERAL REQUIREMENTS

Article 3. The regularization of sanitizing products, according to risk classification, is carried out considering the assessment and management of risk, purpose, and category, and must comply with specific regulations.

Article 4. The following are considered in risk assessment and management:

I – toxicity of the substances and their concentrations in the product;

II – intended use of the products;

III – conditions of use;

IV – occurrence of adverse events or previous technical complaints;

V – likely exposed population;

VI – frequency of exposure and its duration; and

VII – presentation forms.

Article 5. The intended uses of the products are listed in the categories listed in Annex I of this Normative Instruction.

Article 6. Products in the categories Sterilizer, High-Level Disinfectant, Intermediate-Level Disinfectant, Hospital Disinfectant for Fixed Surfaces and Non-Critical Items, Disinfectant/Sanitizer for Hospital Linen, and Enzymatic Detergent must be for professional sale and use.

Article 7. Risk 1 products may only be commercialized after notification has been made through electronic petitioning and published on Anvisa's website.

Article 8. Risk 2 products may only be commercialized after marketing authorization has been granted and published in the Federal Official Gazette (DOU, in Portuguese).

Article 9. Over-the-counter sanitizing products may have a maximum net capacity of 10L or kg (ten liters or kilograms) and must be packaged to facilitate their safe use.

Sole paragraph. Over-the-counter sanitizing products intended for swimming pool disinfection have a maximum quantity limit of 50L or Kg (fifty liters or kilograms).

Article 10. Products for professional sales may be sold in packages of up to 200L or Kg (two hundred liters or kilograms).

Paragraph 1. Products that use automated dosing and dilution system may be sold in packages larger than 200L or Kg (two hundred liters or kilograms).

Paragraph 2. The caption of this article exempts product categories that have limits in specific regulations.

CHAPTER III

ANALYTICAL TOLERANCES

Article 11. For the purposes of prior and fiscal analysis and production control, the acceptable quantitative variation, expressed as a percentage, between the declared and analyzed quantities of each component of the formulation must comply with the limits established in Annex II of this Normative Instruction.

Paragraph 1. For production control purposes, the concentrations of the components in the standard formula may be expressed as intervals.

Paragraph 2. If the concentrations of the components in the standard formula are expressed as intervals, the average concentration of each component must be equal to the value declared in

the notification or marketing authorization, and the interval limits (variation around the average) must comply with the limits established in Annex II of this Normative Instruction.

Paragraph 3. For preliminary analysis purposes, physical-chemical data may be expressed as intervals.

Paragraph 4. Products that have quantitative limits in specific regulations are excluded from the caption of this article.

CHAPTER IV

LABEL SALES

Article 12. When necessary, the company has up to 60 (sixty) days, without extension, to sell previously approved labels, after the publication of a request that may change the label.

Paragraph 1. The sale of labels for risk 1 products is prohibited.

Paragraph 2. The request for a change in the formula of a risk 2 product is exempt from the caption of this article.

CHAPTER V

PROOF OF VALIDITY PERIOD

Article 13. For risk 1 products with a shelf life of up to 36 (thirty-six) months, the presentation of the stability test at the time of electronic application is optional and may be performed by a contracted laboratory or by the company itself.

Sole paragraph. When the shelf life exceeds 36 (thirty-six) months, the stability test report must be attached at the time of application.

Article 14. For risk 2 products, the proposed shelf life must be proven by an accelerated or long-term stability test, presented at the time of marketing authorization.

Paragraph 1. The decrease between the initial and final active ingredient, active ingredient, or active substance content in the accelerated stability test cannot be greater than 5% (five percent).

Paragraph 2. The accelerated stability test must be performed at 54°C ± 2°C (fifty-four degrees Celsius plus or minus two degrees Celsius) for 14 (fourteen) days.

Paragraph 3. For formulations that exhibit significant loss of active ingredient or active substance content due to elevated temperatures, or for which the accelerated stability test conditions do not realistically reproduce product storage, the following times and temperatures must be used:

I – 28 (twenty-eight) days at 50°C ± 2°C (fifty degrees Celsius plus or minus two degrees Celsius);

II – 42 (forty-two) days at 45°C ± 2°C (forty-five degrees Celsius plus or minus two degrees Celsius);

III – 56 (fifty-six) days at 40°C ± 2°C (forty degrees Celsius plus or minus two degrees Celsius);

IV – 84 (eighty-four) days at 35°C ± 2°C (thirty-five degrees Celsius plus or minus two degrees Celsius); or

V – 126 (one hundred and twenty-six) days at 30°C ± 2°C (thirty degrees Celsius plus or minus two degrees Celsius).

Paragraph 4. The projected shelf life based on the accelerated stability test is a maximum of 24 (twenty-four) months.

Paragraph 5. The company that opts for the accelerated stability test must simultaneously initiate a long-term stability test with the same sample until the desired shelf life is reached.

Paragraph 6. The results obtained in the long-term stability test, as provided for in the previous paragraph, must be presented:

I – at the time of the first marketing authorization revalidation;

II – when they do not confirm the results of the accelerated stability test; or

III – when required by the health authority.

Paragraph 7. When the results of the accelerated stability test do not confirm, the company must request a change in the expiration date, based on the results obtained by the long-term stability test.

Paragraph 8. The long-term stability test consists of analyses of the active ingredient or active substance content, performed on the same sample, stored at room temperature, in the following situations:

I – initial analysis (newly produced);

II – intermediate analyses; and

III – final analysis (expiration date).

Paragraph 9. The initial and final analyses must be performed in an accredited laboratory.

Paragraph 10. Intermediate analyses, with frequency determined by the company, may be performed in its own laboratory or outsourced.

Paragraph 11. The variation between the initial and final active ingredient or active substance content in the long-term stability test must comply with the limits established in Annex II.

CHAPTER VI

FINAL PROVISIONS

Article 15. Petitions for regularization of new sanitizing products must fully comply with the provisions of this Normative Instruction from the date it comes into effect.

Paragraph 1. Petitions for revalidation and declarations of interest in continuing to sell sanitizing products must fully comply with the provisions of this Normative Instruction, from the date it comes into effect.

Paragraph 2. Petitions that modify sanitizing products already regulated must specifically comply with the Chapters of this Normative Instruction, from the date it comes into effect, related to the changes they promote.

Article 16. Failure to comply with the provisions of this Normative Instruction constitutes a health violation, subjecting the offender to prosecution and penalties provided for in Law No. 6,437 of 20 August 1977, or any legal instrument that replaces it, without prejudice to applicable criminal and civil liabilities.

Article 17. This Normative Instruction shall come into effect on the date of its publication.

RÔMISON RODRIGUES MOTA

Acting Director-President

ANNEX I

CATEGORIES
Leaf Brightener
Bleach
Algaecide
Bleach
Chlorinated Bleach
Fabric and Clothing Softener
Wax
Degreaser
Acid Descaling Agent
Alkaline Descaling Agent
Water Disinfectant for Human Consumption
High Level Disinfectant
Intermediate Level Disinfectant
Hospital Disinfectant for Fixed Surfaces and Non-Critical Items
Disinfectant for Fruit and Vegetables
Disinfectant for the Food Industry and Related Industries
Disinfectant for Lactation Rooms
Pool Disinfectant
Hospital Clothing Disinfectant
Fabric and Clothing Disinfectant
Special Purpose Disinfectant
General Purpose Disinfectant

Environmental Deodorizer
Sanitary Appliance Deodorizer
Deodorizer for Specific Use
Room Dehumidifier
Anti-rust Detergent
Automotive Detergent
Degreasing Detergent
Enzymatic Detergent
Furniture Cleaning Detergent
Floor Cleaning Detergent
Plastic Cleaning Detergent
Tire Cleaning Detergent
Glass Cleaning Detergent
Dishwashing Detergent
Laundry Detergent
Pre-Wash Detergent
Detergent for Specific Use
General Purpose Detergent
Polishing Detergent for Metal Surfaces
Professional Acid Descaling Detergent
Professional Detergent Solvent Chlorinated Ethylene
Sanitary Detergent
Starching Agent
Sterilizing Agent
Ironing Facilitator

Finisher
Fungicide
Waterproofing Agent
Over-the-Counter Insecticide
Insecticide for Specialized Companies
Amateur Gardening
Dishwashing Agent
Clothing Washing Agent
Aluminum Cleaner
Rubber Cleaner
Shoe Cleaner
Carpet and Rug Cleaner
Leather Cleaner
Furniture Cleaner
Floor Cleaner
Plastic Cleaner
Tire Cleaner
Window Cleaner
Anti-rust Cleaner
Air Conditioner Cleaner
Pool Cleaner
General Purpose Cleaner
Degreasing Cleaner
Molluscicide
Odor Neutralizer

Odor Neutralizer with Antimicrobial Action
Acid Residue Neutralizer
Alkaline Residue Neutralizer
Air Freshener
Antimicrobial Air Freshener
Polisher
Shoe Polisher
Biological Product
Pool Treatment Product
Over-the-Counter Rodenticide
Rodenticide for Specialized Companies
Remover
Repellent
Soap
Sanitizer for the Food Industry
Sanitizer for Hospital Clothing
Sanitizer for Fabrics and Clothing
Specific Purpose Sanitizer
General Purpose Sanitizer
Soap Powder
Drying Brightener
Sealer
Paint/Varnish with Antimicrobial Sanitizing Action
Paint/Varnish with Sanitizing and Disinfectant Action
Stain Remover

ANEXO II -------

Declared quantity of component (%)	**Acceptable variation (%)**
Greater than or equal to 50	2.5
Greater than or equal to 25 and less than 50	5.0
Greater than or equal to 10 and less than 25	6.0
Greater than or equal to 2.5 and less than 10	10.0
Less than 2.5	15.0