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RESOLUTION - RDC NO. 059 OF DECEMBER 17th 2010

Provides for the procedures and technical requirements for the notification and registration of sanitizing products and other measures.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attribution conferred by item IV of art. 11 of the Regulation approved by Decree n. 3,029, of April 16, 1999, and in view of the provisions of item II and §§ 1 and 3 of art. 54 of the Internal Regulations approved pursuant to Annex I of Ordinance no. 354 of Anvisa, of August 11, 2006, republished in the DOU of August 21, 2006 and rectified in the DOU of August 29, 2006, in a meeting held on December 13, 2010,

adopts the following Resolution of the Collegiate Board of Directors and I, Chief Executive Officer, determine its publication:

Art. 1 The technical regulation for procedures and technical requirements for the notification and registration of sanitizing products is approved.

CHAPTER I
INITIAL PROVISIONS

Section I
Objective

Art. 2 This regulation has the objective of preparing, revising, changing, consolidating, standardizing, updating, reducing bureaucracy, establishing definitions, general characteristics, packaging and labeling, technical requirements for the notification and registration of products classified as sanitizing, in order to manage health risks.

Section II
Scope

Art. 3rd This regulation applies to all products defined as sanitizing.

Section III
Definition

Art. 4 For the purposes of this technical regulation, the following definitions are adopted:

I - fiscal analysis: analysis carried out on sanitizing products, on a routine basis, to investigate violations or verify the occurrence of deviations regarding the quality, safety and effectiveness of products or raw materials;

II - prior analysis: analysis carried out on sanitizing products, in order to verify whether they can be notified and registered;

III - category: group of products with the same purpose of use;

IV - active component or active matter or active principle: the one present in the formulation to give effectiveness to the product, according to its purpose, obtained by a manufacturing process (chemical, physical or biological), containing a defined percentage of purity;

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V - disinfection: physical or chemical process that destroys most pathogenic microorganisms on inanimate objects and surfaces, with the exception of bacterial spores;

VI - disinfestation: process that kills, inactivates or repels undesirable organisms in the environment, on objects, inanimate surfaces or on plants;

VII - deodorization: process capable of controlling unpleasant odors, through antimicrobial activity, limited to inhibiting the growth of microorganisms;

VIII - Lethal Dose 50 orally (oral LD50): a single dose of the test substance which, when administered orally, causes the death of 50% of the tested animals.

IX - packaging: casing, container or any form of packaging, removable or not, intended to cover, pack, package, protect or maintain, specifically or not, products dealt with in this regulation;

a) primary packaging: packaging that is in direct contact with the product and which may consist of a container, wrapping or any other form of protection, removable or not, intended for filling or keeping, covering or packaging finished products; It is

b) secondary packaging: packaging whose purpose is to group and protect primary packaging;

X - specialized company: legal entity, private or public, duly constituted, licensed by the competent health or environmental bodies, to provide vector and urban pest control services;

XI - sterilization: process that uses chemical or physical agents to destroy all forms of microbial life, including sporulated ones, and is specifically applied to inanimate objects;

XII - stability study: set of tests carried out to obtain information on the stability of products in terms of previously specified limits, in order to define their expiration date and period of use in packaging and specified storage conditions;

XIII - accredited laboratory: any laboratory, national or foreign, that performs tests and meets the criteria of Inmetro, Standard ISO 17025 or that comply with Good Laboratory Practices - GLP;

XIV - viable microorganism: living and cultivable microorganism in culture media and in specific environmental conditions;

XV - notification: obligation to communicate in advance, by means of an electronic petition to Anvisa, the importation, industrialization, exposure for sale or delivery for consumption of risk 1 sanitizing products;

XVI - odorization: process intended to perfume objects, surfaces and environments by releasing substances;

XVII - main panel: the most prominent area of the label, immediately facing the consumer and where the name of the product appears;

XVIII - secondary panel: other areas of the label containing the information described in regulations;

XIX - corrosive product: one that produces destruction of skin tissue, visible necrosis through the epidermis, and into the dermis, in more than 1 among 3 animals tested, after an exposure of up to 4 hours;

XX - sanitizing product: substance or preparation intended for application on objects, fabrics, inanimate surfaces and environments, with the purpose of cleaning and the like, disinfection, disinfestation, sanitization, deodorization and odorization, in addition to disinfection of water for human consumption, horticultural products and swimming pools;

XXI - sanitizing product for professional use: product that cannot be sold directly to the public and must be applied or handled exclusively by a duly trained professional or a specialized company;

XXII - over-the-counter sanitizing product: product that can be sold directly to the public;

XXIII - registration: Anvisa's private act, after evaluation and concession order by its director, intended to prove the right to manufacture and import a product subject to the regime of Law No.

XXIV - risk: probability of an adverse event occurring on non-target species or damage to the environment;

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XXV - label: printed, lithographed, painted, engraved, pressure-engraved or self-adhesive identification, applied directly to the primary packaging, which cannot be removed or altered during use, transport or storage of the product;

XXVI - sanitization: process that reduces the number of microorganisms to safe levels, in accordance with health standards; It is

XXVII - version: product, under the same name/brand, with the same base formula with regard to active components or active materials or active principles and complementary components, differing between them only by fragrance, dye, or both.

Single paragraph. The value established in item VIII is expressed in unit weight of the test substance per unit mass of body weight of the test animal (mg/ kg).

CHAPTER II
GENERAL REQUIREMENTS

Art. 5th Notification and registration of sanitizing products are carried out taking into account risk assessment and management, purpose, category and must comply with specific regulations.

Art. 6 The following are considered in risk assessment and management:

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

II - purpose of use of the products;

III - conditions of use;

IV - occurrence of adverse events or previous technical complaints;

V - probably exposed population; VI - frequency of exposure and its duration; It is

VII - forms of presentation.

Art. 7 Only companies that have a Company Operation Permit - AFE, with the activities: manufacture, produce or import sanitizing products, may notify or register the products contemplated in this regulation.

Art. 8 Companies legally authorized to manufacture, store, distribute, transport, fractionate or import sanitizing products are subject to verification of compliance with Good Manufacturing and Control Practices, requested by the competent health authority through inspection, pursuant to Law No. 6,360, of September 23, 1976 and its amendments.

Art. 9 The manufacture, import and sale of products whose formulation contains: I - component not allowed; II - component that exceeds the limit established in a specific regulation; or III - component that has proven mutagenic, teratogenic or carcinogenic effects in mammals.

Single paragraph. Exclusive products for export are excluded from this article.

Art. 10. Products manufactured exclusively for export must comply with Resolution RDC No. 38, of April 28, 2000 and its updates or other regulations.

Art. 11. Notification or registration of versions of a product is done under the same process number.

Art. 12. Risk 1 products can only be marketed after notification made through the fully electronic petition and published on Anvisa's page, on the world wide web - internet.

Art. 13. Risk 2 products can only be marketed after the granting of registration published in the Federal Official Gazette.

CHAPTER III
CLASSIFICATIONS

Art. 14. Sanitizing products are classified according to risk, purpose, sale and use.

Section I
Regarding the Risk

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Art. 15. For notification and registration purposes, sanitizing products are classified as risk 1 and risk 2, respectively.

Subsection I
Risk Products 1

Art. 16. Sanitizing products are classified as risk 1 when:

I - present oral LD50 for rats greater than 2000mg/kg of body weight for liquid products and greater than 500mg/kg of body weight for solid products;

II - the pH value in pure form, at a temperature of 25º C (twenty-five degrees Celsius), is greater than 2 or less than 11.5;

III - do not present characteristics of corrosivity, antimicrobial activity, disinfestation action and are not based on viable microorganisms; It is

IV - do not contain in their formulation one of the following inorganic acids:

a) hydrofluoric (HF);

b) nitric (HNO3);

c) sulfuric (HtwoONLY4); or

d) its salts that are released in the conditions of use of the product.

§1 The values established in item I must be evaluated for the pure product.

Paragraph 2 In item I, the oral LD50 theoretical calculation method recommended by the WHO will be admitted.

§3 In the case of products treated in item II whose pH cannot be measured in pure form, these must be evaluated in the dilution at 1% w/w.

Subsection II
Risk Products 2

Art. 17. Sanitizing products are classified as risk 2 when:

I - present oral LD50 for rats greater than 2000mg/kg of body weight for liquid products and greater than 500mg/kg of body weight for solid products;

II - the pH value in pure form, at a temperature of 25º C (twenty-five degrees Celsius), is equal to or less than 2 or equal to or greater than 11.5;

III - present characteristics of corrosivity, antimicrobial activity, disinfestation action or are based on viable microorganisms; or

IV - contain in their formulation one of the following inorganic acids:

a) hydrofluoric (HF);

b) nitric (HNO3);

c) sulfuric (H2SO4); or

d) its salts that are released in the conditions of use of the product.

§1 The values established in item I must be evaluated for the product in the final dilution for use.

Paragraph 2 In item I, the oral LD50 theoretical calculation method recommended by the WHO will be admitted.

§3 In the case of products treated in item II whose pH cannot be measured in pure form, these must be evaluated in the dilution at 1% w/w.

Section II
Purpose

Art. 18. Sanitizing products are classified according to their purpose in:

I - cleaning in general and the like;

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II - disinfection, sterilization, sanitization, deodorization, in addition to disinfection of water for human consumption, horticultural products and swimming pools; It is

III - disinfestation.

Single paragraph. The purposes are arranged in the categories listed in Annex II of this Resolution.

Section III
Regarding Sales and Employment

Art. 19. Sanitizing products are classified for sale and use in:

I - over-the-counter products; It is

II - products for professional use or sales restricted to a specialized company.

Single paragraph. Products in the sterilizer, high-level disinfectant, intermediate-level disinfectant, hospital disinfectant for semi-critical items, hospital disinfectant for fixed surfaces and non-critical items, disinfectant/ sanitizer for hospital linen and enzymatic detergent categories must be for professional use.

Art. 20. Over-the-counter products may be marketed in packages of a maximum of 5 liters or kilograms, except when there is a restriction in a specific rule.

Single paragraph. Products intended for the disinfection of swimming pools have a maximum quantitative limit of 50 liters or kilograms.

Art. 21. Products for professional use or sales restricted to a specialized company may be marketed in packages of a maximum of 200 liters or kilograms.

Single paragraph. Products that use an automated dosing and dilution system can be marketed in packages of over 200 liters or kilograms.

CHAPTER IV
REQUIREMENTS FOR NOTIFICATION

Art. 22. Products classified as risk 1, to be notified, must comply with the provisions of Resolution RDC nº 42, of August 13, 2009 and updates, in addition to the requirements of this regulation.

CHAPTER V
REGISTRATION REQUIREMENTS

Art. 23. For the registration of products classified as risk 2, the following documents must be presented:

I - forms issued by the electronic petition system;

II - original proof of payment of the sanitary surveillance inspection fee (GRU);

III - reports, stability study and reports required by specific rule;

IV - pH report (can be carried out by the company itself);

V - two-part label model, printed on A4 paper, with a resolution that allows the reading of the words, with the colors and shades of the final label;

VI - drawing, sketch or photo of the package;

VII - general data of the company;

VIII - copy of the health permit or request for renewal (both for the current year); It is

IX - copy of the health permit or renewal request (both for the current year) of the outsourced company, if applicable.

Single paragraph. In item V, if there is a need to adjust to fit the A4 size, the scale ratio must be informed.

CHAPTER VI
ANALYTICAL TOLERANCES

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Art. 24. For purposes of prior and fiscal analysis and production control, the acceptable quantitative variation, expressed in percentage (%), between the declared and analyzed quantity of each component of the formulation, must comply with the limits established in the table contained in Annex I of this Resolution.

§1º For purposes of production control, the concentrations of the components in the standard formula can be expressed by intervals.

§2 In case the concentrations of the components in the standard formula are expressed by intervals, the average concentration of each component must be equal to the value declared in the notification/registration and the limits of the interval (variation around the mean) must comply with the acceptable variations of the table contained in Annex I of this Resolution.

§3º Excluded from this variation are products that present quantitative limits in specific regulations.

§4 For purposes of prior analysis, the physical chemical data may be expressed by intervals.

CHAPTER VII
PACKAGING AND LABELING

Art. 25. The primary packaging material must have adequate composition and porosity so as not to allow the occurrence of:

I - chemical reactions between the product and the packaging;

II - change of color of the product;

III - odor transfer;

IV - migration of substances to the product; or

V - migration of the product to the external environment.

Art. 26. The package must be well sealed, with a closure that prevents leaks or any accidents and in such a way that it can be closed several times during use, without the risk of contact with the product, making it difficult to open accidentally or casually during the period of use of the product.

Art. 27. The use of packaging and labeling that allow false interpretation, error or confusion as to the origin, origin, nature, composition or quality that attributes to the product purpose or characteristic different from that for which it is intended is prohibited.

Art. 28. It is forbidden to reuse used packages of food, beverages, dietetic products, medicines, drugs, hygiene products, cosmetics and perfumes, for packaging sanitizing products.

Art. 29. Mandatory information cannot be written on parts that are removable for use, such as lids, safety locks and others, which become unusable when opening the package.

Single paragraph. It is prohibited to inscribe the batch, date of manufacture and expiry date on parts that are removable for use.

Art. 30. When the surface of the primary packaging does not allow the indication of all the labeling words, it must contain, obligatorily, at least:

I - the name of the product;

II - active component or active substance or active ingredient;

III - batch;

IV - expiry date; It is

V - warning: "Before using, read the instructions in the explanatory prospectus" or similar sentence.

Single paragraph. Other information that is not on the surface of the primary packaging must be indicated in the prospectus or equivalent, which must accompany the product.

Art. 31. When necessary, the company has up to 60 (sixty) days, without extension, to dispose of the previously approved labels, after the publication of a claim that may change the label.

§1 It is prohibited to dispose of labels for risk 1 products.

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Paragraph 2 This article excludes the request for modification of the risk product formula 2.

Art. 32. The wording on the label must follow specific rules.

CHAPTER VIII
EXPIRATION DATE PROOF

Art. 33. For risk 1 products, with a shelf life of up to 36 months, presentation of the stability study at the time of the electronic application is optional, and may be carried out by a contracted laboratory or by the company itself.

Single paragraph. The study file must be attached at the time of application when the period of validity exceeds 36 months.

Art. 34. For risk 2 products, the proposed shelf life must be proven through an accelerated or long-term stability study, presented at the time of registration.

§1 The decrease between the initial and final active component or active matter or active ingredient content, in the accelerated stability study, cannot be greater than 5%.

§2 The accelerated stability study must be carried out at 54º C ± 2º C for 14 days.

§3 For formulations that show a significant loss of active component or active material or active ingredient content due to elevated temperature or whose conditions of the accelerated stability study do not realistically reproduce the storage of the product, the following times and temperatures must be used:

I - 28 days at 50º C ± 2º;

II - 42 days at 45º C ± 2º;

III - 56 days at 40º C ± 2º;

IV - 84 days at 35º C ± 2º; or

V - 126 days at 30º C ± 2º.

§4 The projected shelf life based on the accelerated stability study is a maximum of 24 months.

§5 The company that opts for the accelerated stability study must start, concomitantly, a long-term stability study with the same sample until the intended validity period is reached.

§6 The results obtained in the long-term stability study, provided for in the previous paragraph, must be presented:

I - at the time of the first revalidation of the registration; or

II - when they do not confirm the results of the accelerated stability study; or

III - when required by the sanitary authority.

§7 When the results of the accelerated stability study are not confirmed, the company must request a change in the expiration date, according to the result achieved by the long-term stability study.

§8 The long-term stability study comprises analyses, regarding the content of active component or active matter or active principle, carried out on the same sample, stored at room temperature, in the following situations:

I - initial analysis (newly produced);

II - intermediate analyses; It is

III - final analysis (expiry date).

§9 The initial and final analyzes must be carried out in an accredited laboratory.

§10. Intermediate analyses, with a periodicity determined by the company, can be carried out in its own laboratory or outsourced.

§11. The variation between the initial and final active component or active matter or active ingredient content, in the long-term stability study, must comply with the limits established in Annex I.

CHAPTER IX
FINAL AND TRANSITIONAL PROVISIONS

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Art. 35. As of the effectiveness of this Resolution, the notification and registration of new products must fully comply with this regulation.(Rectified by DOU No. 04, of January 6, 2011)

Art. 36. Products already notified and registered that do not fully comply with this regulation must comply at the time of revalidation or the first change request.

Art. 37. Failure to comply with the provisions contained in this Resolution and in the regulation approved by it constitutes a sanitary infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to applicable civil, administrative and criminal liabilities.

Art. 38. Resolution RDC No. 184, of October 22, 2001, Resolution RE No. 3169, of September 22, 2006, items 3.2 and 3.3 of the Annex to Resolution RDC No. 38, of April 28, 2000 and Resolution RDC No. 32, of February 5, 2002 are hereby revoked.

Art. 39. This Resolution enters into force within ninety days from the date of its publication.

DIRCEU RAPOSO DE MELLO

ANNEX I

Declared quantity of the 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

ANNEX II

CAT EGORIES
SHEET BRINDER
BLEACH
Algaecide
BLEACH
CHLORINATED BLEACH
FABRIC AND CLOTHING SOFTENER
WAX
DEGRAXANT
ACID DESCRUSTANT
ALKALINE DESCRUSTANT
WATER DISINFECTANT FOR HUMAN CONSUMPTION
HIGH LEVEL DISINFECTANT
INTERMEDIATE LEVEL DISINFECTANT
HOSPITAL DISINFECTANT FOR SEMI-CRITICAL ITEMS
HOSPITAL DISINFECTANT FOR FIXED SURFACES AND NON-CRITICAL ITEMS
DISINFECTANT FOR VEGETABLES
DISINFECTANT FOR FOOD AND RELATED INDUSTRY
DISINFECTANT FOR DAIRY POWDERS
SWIMMING POOL DISINFECTANT

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DISINFECTANT FOR HOSPITAL CLOTHES
DISINFECTANT FOR FABRIC AND CLOTHING
DISINFECTANT FOR SPECIFIC USE
DISINFECTANT FOR GENERAL PURPOSE
ENVIRONMENTAL DEODORANT
DEODORANT FOR SANITARY APPLIANCES
DEODORANT FOR SPECIFIC USE
ENVIRONMENT DEHUMIDIFIER
ANTI-RUST DETERGENT
AUTOMOTIVE DETERGENT
DEGREASING DETERGENT
ENZYME DETERGENT
FURNITURE CLEAN DETERGENT
FLOOR CLEANING DETERGENT
PLASTICS CLEANING DETERGENT
TIRE CLEANING DETERGENT
WINDOW CLEANING DETERGENT
DISHWASHING DETERGENT
DETERGENT FOR WASHING CLOTHES
DETERGENT FOR PRE WASHING
DETERGENT FOR SPECIFIC USE
DETERGENT FOR GENERAL PURPOSE
POLISHING DETERGENT FOR METAL SURFACES
PROFESSIONAL ACID DESCREAMER DETERGENT
PROFESSIONAL DETERGENT CHLORINATED ETHYLENE SOLVENT
SANITARY DETERGENT
IRONING
STERILIZER
FACILITATOR TO IRON CLOTHES
FINISHER
FUNGICIDE
WATERPROOFING
FREE SALE INSECTICIDE
INSECTICIDE FOR SPECIALIZED COMPANIES
AMATEUR GARDENING
DISHWASHER
WASH CLOTHES
CLEAN ALUMINUM
RUBBERS CLEANER
CLEAN FOOTWEAR
CLEAN CARPETS AND RUGS
LEATHER CLEANER
FURNITURE CLEANER
CLEAN FLOORS
CLEAN PLASTICS
TIRES CLEANER
GLASS CLEANER
ANTI-RUST CLEANER
AIR CONDITIONING CLEANER
POOL CLEANER
GENERAL PURPOSE CLEANER
DEGREASING CLEANER
molluscicide

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ODOR NEUTRALIZER
ODOR NEUTRALIZER WITH ANTIMICROBIAL ACTION
ACID WASTE NEUTRALIZER
ALKALINE WASTE NEUTRALIZER
ODORIZANT
ODORIZANT WITH ANTIMICROBIAL ACTION
POLISHER
SHOE POLISHER
ORGANIC PRODUCT
FREE SALE RATICIDE
RATICIDE FOR SPECIALIZED COMPANIES
REMOVER
REPELLENT
SOAP
SANITIZER FOR FOOD INDUSTRY
SANITIZER FOR HOSPITAL CLOTHES
SANITIZER FOR FABRIC AND CLOTHING
SANITIZER FOR SPECIFIC USE
SANITIZER FOR GENERAL USE
SAPONACEOUS
BRIGHTENING DRYER
SEALER
STAIN REMOVER