

National Health Surveillance Agency**www.anvisa.gov.br****Public Consultation No. 489 of March 23, 2018
DOU of 03/27/2018**

The Collegiate Board of the National Sanitary Surveillance Agency, in the use of attributions conferred by art. 15, III and IV allied to art. 7, III, and IV, of Law No. 9,782, of June 26, January 1999, and to art. 53, III, §§ 1 and 3 of the Internal Regulations approved in Annex I of the Resolution of the Collegiate Board of Directors - RDC n ° 61, of February 3, 2016, resolves submit to the public consultation, for comments and suggestions from the general public, normative act in the Annex, as resolved at a meeting held on March 6, 2018, and I, the Chief Executive Officer, determine its publication.

Art. 1 The thirty-day deadline for sending comments and suggestions to the text of the technical regulation for sanitizers categorized as bleach based on sodium hypochlorite or calcium hypochlorite and makes other arrangements.

Single paragraph. The period covered by this article will begin 7 (seven) days after the date of publication of this Public Consultation in the Official Gazette of the Union.

Art. 2 The proposal for a normative act will be available in its entirety on the Anvisa and the suggestions should be sent electronically by completing form specific, available at the Address: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=37495

Paragraph 1 The contributions received are considered public and will be available to anyone interested by means of tools contained in the electronic form, in the menu "Outcome", including during the consultation process.

§2. Upon completion of the electronic form, it will be made available to the concerned the protocol number of the registration of its participation, being dispensed with the postcard or face-to-face protocol of physical documents with the Agency.

§3 In case of limitation of access of the citizen to computerized resources will be allowed sending and receiving suggestions in writing, on physical medium, during the consultation period, to the following address: National Agency of Sanitary Surveillance / COSAN / GHCOS, SIA section 5, Special Area 57, Brasília-DF, CEP 71.205-050.

§4 Exceptionally, international contributions may be the following address: National Health Surveillance Agency / International Affairs - AINTE, SIA section 5, Special Area 57, Brasília-DF, CEP 71.205-050.

Art. 3. Once the term stipulated in art. 1st, the National Health Surveillance Agency It will promote the analysis of contributions and, at the end, publish the result of the public the Agency's website.

Single paragraph. The Agency may, as necessary and for reasons of convenience and opportunities, to articulate with agencies and entities involved with the subject, as well as those who have expressed an interest in the matter, to support further discussions and the final deliberation of the Collegiate Board of Directors.

JARBAS BARBOSA DA SILVA JR.

Page 2

ATTACHMENT

PROPOSAL IN PUBLIC CONSULTATION

Process nº: 25351.612376 / 2015-24

Subject: Proposal for a technical regulation for sanitizers categorized as bleaches based on sodium hypochlorite or calcium hypochlorite.

Regulatory Agenda 2017-2020: Item 9.3

Processing Regime: Common

Responsible area: COSAN / GHCOS

Rapporteur: Fernando Mendes Garcia Neto

RESOLUTION - RDC No. XX, OF XX OF XXX OF 2017

Provides technical regulation for sanitizing products categorized as base of sodium hypochlorite or calcium hypochlorite and makes other arrangements.

The Collegiate Board of the National Health Surveillance Agency, in the use of the Article III, Section IV, 15 of Law No. 9,782 of January 26, 1999, item II, and §§ 1 and 3 of art. 54 of the Internal Regulations approved in accordance with Annex I of Administrative Rule no. ANVISA, dated August 11, 2006, republished in the Official Gazette of August 21, 2006, and its updates, in view of the provisions of items III, of art. 2, III and IV of art. 7th of the Law No. 9,782 of 1999 and the Program for Improvement of the Regulatory Process of the Agency, established by Administrative Rule no. 422, of April 16, 2008, at a meeting held in XX of XXX of 2014, adopts the following Resolution of the Collegiate Board of Directors and I, the Chief Executive Officer, I determine its publication:

Article 1 The technical regulation on sanitizing products based on hypochlorites in the Annex to this Resolution.

Article 2 This Resolution incorporates into the national legal order the Resolution GMC MERCOSUR n ° 13/15 "MERCOSUR Technical Regulation for Sanitary Products Based on Hypochlorite Additives", with revocation of Resolution GMC n. 57/98.

Art. 3 The provisions to the contrary are revoked, in particular the Resolution of the Board of Directors Collegiate n. 109, of September 6, 2016.

Art. 4. Failure to comply with the provisions contained in this Resolution and in the regulation thereof approved is a sanitary infraction, pursuant to Law no. 6,437 of August 20, 1977, without civil, administrative and penal liabilities.

Article 5 This Resolution shall enter into force on the date of its publication.

ATTACHMENT

TECHNICAL REGULATION FOR HEALTHY PRODUCTS BASED ON HYPOCHLORITES ADDITIVES

In the light of the Public Health campaigns carried out by the health authorities of the States, as well as the customs of uses and classifications corresponding to the chlorinated products for water disinfection, the products **LAVANDINA WATER / WATER SANITARY / CHLORATED WATER / CHLORINE OR FARM ARE NOT INCLUDED IN THIS REGULATION.**

SCOPE:

LAVANDINA WATER ADDITIVATED / ADDITIVE CONCENTRATED (ARGENTINA AND PARAGUAY)

Page 3

CONCENTRATED TARGETER / ALVEJANTE (BRAZIL)

CONCENTRATED ADDITIVE / ADDITIVE CHLORINATED WATER (URUGUAY)

CHLORO OR LEJIA ADITIVADA / CHLORO OR LEJIA ADITIVADA CONCENTRADA (VENEZUELA)

DEFINITION:

It is understood by **WATER lavandina additive / BLEACH THE HYPOCHLORITE BASE OF SODIUM OR CALCIUM / ADDED CHLORINE WATER / CHLORINE OR ADDITIVE** solution based on Sodium or Calcium Hypochlorite with an Active Chlorine content equal to or greater than 2.0% w / w and less than or equal to 3.9% w / w or its equivalent in g / L, the purpose of which is bleaching and / or disinfection in general. These products may contain coloring and / or detergents and / or flavorings and stabilizers.

It is understood by **lavandin additives CONCENTRATED WATER / BASED WHITENING OF SODIUM HYPOCHLORITE OR CONCENTRATED CALCIUM / CHLORATED WATER ADDITIVATE CONCENTRATE / CHLORINE OR LEAD CONCENTRATED ADDITIVES**, the solution to base of Sodium or Calcium Hypochlorite with an Active Chlorine content equal to or greater than 4.0% w / w of less than or equal to 6.0% w / w or its equivalent in g / L, the purpose of which is bleaching and / or disinfection in general. These products may contain coloring and / or detergents and / or flavorings and stabilizers.

Note: the % w / w of active chlorine defined in each case corresponds to the value at packaging.

NAME:

Due to customs and uses in each of the markets where the product is marketed currently, the current denominations are maintained as equivalent, and can be identified as:

LAVANDINA WATER ADVISED / ADDITIVE CONCENTRATED (ARGENTINA and PARAGUAY)

CONCENTRATED TARGETER / ALVEJANTE (BRAZIL)

CONCENTRATED ADDITIVE / ADDITIVE CHLORINATED WATER (URUGUAY)

USE / RESTRICTION OF USE:

For bleaching and / or disinfection in general.

Do not use for disinfection of water for human consumption.

Do not use for food disinfection.

CONCENTRATION:

The concentration of active chlorine for bleach must be greater than or equal to 2.0% w / w or g / L and less than or equal to 3,9% w / w or its equivalent in g / L at the time of packaging.

Page 4

The concentration of active chlorine for concentrated bleaches should be greater than or equal to 4.0% w / w or its equivalent in g / L and less than or equal to 6.0% w / w or its equivalent in g / L at of the container.

The maximum pH of the pure product should be 13.5.

DECLARED CONCENTRATIONS:

The concentrations of active chlorine declared on the label correspond to the value at the time of packaging and the expiry date.

STABILIZER:

The product may contain as stabilizers Sodium Hydroxide, Sodium Carbonate or Calcium, Sodium or Calcium Chloride or Sodium Silicate.

Other stabilizers may be used when they are not restricted.

LOT / DEPARTMENT IDENTIFICATION:

The lot / departure must be identified.

It can be through the date of manufacture (day / month / year) or by an alphanumeric code.

EXPIRATION DATE:

It will be 180 days from the date of manufacture, unless stability that proves a longer period of validity.

The concentration of active chlorine at the end of the validity period shall be that declared by the company. It will be accepted as proof of stability, the presentation of efficacy trials antimicrobial at the end of the shelf-life of the product at the declared maximum dilution of use.

It can be indicated as:

1. "Valid until ... (month / year)"
2. "expiry date: ... days or months or years from the date of manufacture."
3. "Use until ... (month / year)"

LABELING

(a) the text of the label must be legible, indelible, in the language of the country in which it is to be marketed, being able to be written simultaneously in other languages. Can not be recorded on high or low relief directly on the packaging.

b) THE LABELS MUST INCLUDE:

1 - NO MAIN PANEL:

1. - Name of the product
2. - Trademark or trade name
3. - Net content
4. - Warnings

- - The phrase "Mode of use: if the treated surface comes into contact with food, rinse it before use. "
- - For concentrated products: "Concentrated product. Use only as label instructions. "
- - For concentrated products, the phrase " **CONCENTRATED PRODUCT** " must be in highlighted, in upper case and in bold, the letter size being equal to 1/3 of the the letter or brand name of the product.
- - The phrases: " **Do not use for disinfection of water for human consumption.**", "Use only as directed on the label. " and " **Do not use for disinfection of food.** " should be highlighted or in bold print, with a size 50% greater than the letter size of the general text of the label, with a minimum of 3 mm height.

2 - ON THE SECONDARY PANEL:

1. - Registration number of the titular company, of third parties, when applicable, and of the product. The form of identification shall be subject to the legislation in force of each State Party.
2. - Name, address and telephone number of the company holding the product.
3. - Country of origin of the product.
4. - Instructions for use: should be clear and simple. If it is necessary to use a should be in common use for the consumer or should accompany the consumer. product. The dilution of use, expressed as a percentage, proportion of the product to be diluted or other practical measures, including the equivalent in the metric system.
5. - When the surface of the packaging does not allow the inclusion of the mode of use, precautions and special precautions, these should be indicated in prospectuses must be accompanied by the product and the warning on the packaging must be " **BEFORE USING READ THE EXPLANATORY PROSPECTUS INSTRUCTIONS** ".
6. - Composition: indicate active principles and other components of importance internationally accepted technical name, with its concentration and the other components of the formulation by their function.

7. - Indication of active chlorine concentration expressed as% w / w or its equivalent in g / L at the time of packaging.
8. - Indication of active chlorine concentration expressed as% w / w or its equivalent in g / L at the end of the validity period.
9. - Identification of departure or manufacturing batch.
10. - Indicate the expiration date, together with the date of manufacture, or indicate the date of due date.
11. - Instructions for storing the product.
12. - The phrase " **KEEP OUT OF REACH OF CHILDREN AND ANIMALS** ".
13. - The phrase " **DO NOT MIX WITH OTHER PRODUCTS. THE MIXTURE WITH ACIDS OR PRODUCTS BASED ON AMMONIA GENERATES TOXIC GASES.** ".
14. - Telephone of the Poison Center.
15. - Care and maintenance:
 - - The phrase "Keep the product in its original packaging."
 - - The phrase "For product quality preservation, keep it protected from the sun and of the heat. "

16. - Caring for accidents:

17. - The phrase "In case of contact with skin or eyes, rinse immediately with water current in abundance. If swallowed, do not induce vomiting. In case of inhalation, take the person to a well ventilated place. In all cases, consult the health or Poison Center, leading to packaging or product labeling. "

3 - ON THE MAIN OR SECONDARY PANEL:

1. - Precautionary statements:

- "CAUTION: IRRITANT." Or the irritant product pictogram (St. Andrew's Cross), according to the regulations of each State Party.
- "Avoid contact with eyes and skin".
- "Avoid inhalation of product."
- Do not ingest.
- "Do not use the packaging for other purposes."
- "Wash the objects / utensils used for measurement before reusing them".

2. - The warning phrase for concentrated products: " **CAUTION: PRODUCT FOCUSED.** ".

Comments:

Under no circumstances may the label indicate: "Non-toxic", "Safe", "Non-hazardous", "Non-hazardous" or other similar indications; nor should superlative terms be used, such as "O better, "" Excellent treatment, "" Incomparable "or similar.

PROOF OF ANTIMICROBIAL PRODUCT EFFECTIVENESS

Disinfection products with use concentrations of 3.0 g / L or more will proven antimicrobial resistance by the submission of active chlorine in the use dilution, after 10 minutes of preparation of the solution.

Disinfection products with concentrations of use of less than 3,0 g / l must its antimicrobial efficacy through the presentation of laboratory tests on the dilution of

Where there are no methodologies of the above institutions, the Sanitary Authority competent authority of each State Party shall examine the methods presented on a case-by-case basis.

PACKING

a - The packaging material must have adequate composition and porosity, so that chemical reactions between the product and the packaging that changes in the color of the product, transfer of odors or migration of toxic substances to the product, as well as the migration of the product to the external environment. It is at the discretion of each Accepting the validation of the properties of packaging this paragraph.

b - The packages must be opaque and hermetically closed, in order to guarantee the effectiveness of the product during its period of validity.

c - Packagings must be difficult to break, in order to minimize possible accidents during storage and use.