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RESOLUTION OF THE COLLEGIATE DIRECTORATE – RDC N° 213, OF JANUARY 23, 2018

(Published in DOU n° 17, on January 24, 2018)

Sets the terms for display for sale and commercialization of smoking products derived from tobacco.

The Collegiate Directorate of the National Agency for Health Oversight (ANVISA - *Agência Nacional de Vigilância Sanitária*), in the exercise of the attributes conferred upon it by Art. 15, III and IV, in conjunction with Art. 7, III, and IV, of Law n° 9.782, of January 26, 1999, Art. 53, V, §§ 1 and 3 of the Internal Regimen approved pursuant to the terms of Annex I of Resolution of the Collegiate Directorate - RDC n° 61, of February 3, 2016, resolves to adopt the following Resolution of the Collegiate Directorate, as decided at a meeting held on January 16, 2018, and I, the Chief Executive Officer, order its publication.

CHAPTER I

INITIAL PROVISIONS

Art. 1 The requirements for the display for sale of smoking products derived from tobacco that are sold in this country, and other provisions relating to the commercialization of such products are hereby established.

Art. 2 Display racks or cases for these products at points of sale must contain all health warnings concerning the risks resulting from the use of tobacco, as established by Law n° 9.294/96 and by Decree n° 2.018, of 1996, and their amendments, and specified in this Resolution.

Art. 3 This Resolution applies to all smoking products derived from tobacco commercialized in the national territory, domestically produced or imported, and the display of such products in display racks or cases at points of sale.

Art. 4 For the purposes of this Resolution, the following definitions shall apply:

I - Health warning: a graphic composition containing a written health warning, as per the template in Annex II of this Resolution;

II – Standard health warning: a graphic composition containing a written health warning, accompanied by an image, as per the template in Annex I of this Resolution;

III - Package: wrapping, receptacle or any kind of packaging intended to contain smoking products derived from tobacco, and classified as follows:

a) Primary package: a covering that packages the smoking product derived from tobacco, intended for the end consumer; and



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b) Secondary package: the outer covering of the product, which covers more than one primary package, whether or not it is intended for the end consumer.

IV – To display: the act of presenting something to be seen, to show or display smoking products derived from tobacco for sale in display racks or cases, exclusively at points of sale;

V- Display rack or case: a place intended exclusively for the display and placement of smoking products derived from tobacco intended exclusively for direct sale to the consumer;

VI - Point of sale: an area or fixed space, physically demarcated, located inside a commercial establishment and intended for the display and sale of smoking products derived from tobacco;

VII - Smoking product: a manufactured product, whether or not it is derived from tobacco, that contains leaves or leaf extracts or other parts of plants in its composition;

VIII – Smoking product derived from tobacco: any manufactured smoking product that contains tobacco in its composition; and

IX – Advertising for smoking products derived from tobacco: the display and any kind of announcement, whether via electronic means, including the internet, in print, or any other kind of communication to the public, whether or not it is addressed to consumers of products, for the purpose of promoting, propagating, disseminating, persuading people to smoke, selling or encouraging the use of smoking products derived from tobacco, either directly or indirectly.

CHAPTER II

DISPLAY OF PRODUCTS FOR SALE

Art. 5 Advertising for any smoking product derived from tobacco is prohibited anywhere in the national territory, with the sole exception of displays of products at points of sale, through the arrangement of their packages in display racks or cases, fixed in the interior part of the point of sale, as long as it is accompanied by health warnings, the message of prohibition of sale to minors under the age of eighteen, and the respective price lists, as set forth in this Resolution.

§1 The following things are also considered advertising media and are subject to the prohibition set forth in the heading of this article:

I - Catalogues of products derived from tobacco, whether in printed or digital form, except for those intended exclusively for merchants for purposes of doing business with manufacturers or importers, which must contain only the product type, the package type and the brand name, as registered with ANVISA, as well as the respective prices;



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II Any kind of communication or use of the brand name or element that identifies the brand of the product derived from tobacco, such as a logo, a symbol, a slogan or character, on any product, with the exception of the product itself that is already registered with ANVISA;

III- Any kind of communication, recommendation or commercial action with the purpose, effect or likely effect of promoting, directly or indirectly, a tobacco product or its consumption;

IV- Sponsorship of cultural or athletic activities;

V – Conducting a market survey of the public through any kind of promotional approach.

§2 Display racks or cases must contain only the products displayed for sale and the respective health warnings, message of prohibition of sale to minors under the age of eighteen and price lists.

§3 Price lists must contain only the brand names of the products, the names of the manufacturing and importing companies, and the respective prices.

§4 The use of posters, panels, bills or any device or visual, graphic, sound, sensory or movement or lighting device, either inside the display rack or case, or placed outside, that highlights products or a specific brand, is included in the prohibitions contained in this article.

§5 The prohibition contained in the foregoing paragraph concerning lighting does not apply to the establishment's own lighting, as long as it does not seek to emphasize display racks or cases.

§6 It is prohibited to impede or partially or totally cover visibility of health warnings and the message of prohibition of sale to minors under the age of eighteen in display racks or cases.

Art. 6 The graphic composition consisting of the standard health warning, the health warning and the message of prohibition of sale to minors under the age of eighteen, as per the templates available at ANVISA's web portal, shall occupy at least 20% (twenty percent) of the area of each one of the surfaces visible to the public of the display racks or cases at the point of sale, as follows:

I The standard health warning, as per the template in Annex I of this Resolution, printed legibly and prominently, which must occupy, 70% (seventy percent) of the area of the graphic composition;

II The health warning, as per the template in Annex II of this Resolution, printed legibly and prominently, which must contain 3 (three) elements: the general warning sign, the statement "Danger: Toxic Product" in red letters (PANTONE 485C or the corresponding CMYK value), in bold, capital letters in the Arial font, and the statement on the harmful effects caused by tobacco in bold, white letters, Arial font, all printed on a black background (PANTONE Process Black C



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or the corresponding CMYK value), which must occupy 25% (twenty-five percent) of the surface area of the graphic composition; and

III The message of prohibition of sale to minors under the age of eighteen - "Sale prohibited to anyone under the age of 18," as per the template in Annex III of this Resolution, printed legibly and prominently, in white, bold letters, Arial font, on a red background (PANTONE 485C or the corresponding CMYK value), which must occupy 5% (five percent) of the surface area of the graphic composition.

Sole paragraph. The graphic composition of the warnings described in the heading of this article must be presented in one single piece in the central part of the surface area of each one of the surfaces visible to the public of the display racks or cases, as per the template in Annex IV of this Resolution, without altering the proportional relation among its elements, or that of its graphic parameters.

Art 7 Smoking products derived from tobacco must be displayed as far as possible from candy, chewing gum, sweets, chocolates, ice cream and popsicles and toys, in order not to facilitate their visibility by children and adolescents.

CHAPTER III

COMMERCIALIZATION OF PRODUCTS

Art 8 With regard to the commercialization of smoking products derived from tobacco, the following things are prohibited:

- I- Making the sale of other products, whether in a single package or not, or of services of any kind, contingent upon the purchase of smoking products derived from tobacco;
- II- Commercializing smoking products derived from tobacco over the internet anywhere in the national territory;

III- The importation, exportation, commercialization, transport, delivery or any other action, by a natural or juridical person, of smoking products derived from tobacco through the means of express and postal delivery;

IV- Distribution of free samples of smoking products derived from tobacco;

V- Distribution of complimentary gifts relating to smoking products derived from tobacco. Sole paragraph. In relation to sub-paragraph III, exportation by express delivery conducted by an industrial establishment that has a special registration with the Bureau of Federal Revenue of Brazil (*Secretaria de Receita Federal do Brasil*), is excepted from the prohibition established in the heading.

CHAPTER IV

FINAL AND TRANSITORY PROVISIONS

Art 9 The provisions set forth in this law are in compliance with what is set forth in the Framework Convention on Tobacco Control of the World Health Organization, adopted by the member countries of the World Health Organization on May 21, 2003, and signed by Brazil on June 16, 2003, promulgated by Decree nº 5.658, of January 2,

*This text does not replace the one(s) published in the **Diário Oficial da União**.*



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2006, and observe the Guidelines for its implementation, approved at the Conference of the Parties.

Art. 10 Use is permitted of display racks or cases in compliance with the specifications contained in this Resolution, even before its entry into force.

Art. 11 Exclusively for compliance with what is set forth in Resolution of the Collegiate Directorate - RDC nº 195, of 2017, adjustments made in packaging must be previously submitted to ANVISA, up until the date of entry into force of the cited law, and they are susceptible to immediate implementation, without a prior statement by ANVISA.

§1 To comply with what is set forth in the heading of this article, the submission of adjustments in packaging already approved by ANVISA must be done through a petition for an Amendment, and must be accompanied by all the documentation required for the matter.

§2 The immediate implementation of alterations in packaging, as cited in the heading, does not at any preclude analysis by ANVISA, at any time, of the required documentation.

§3 The authenticity and veracity of the information supplied to ANVISA are the responsibility of the holder of the registration.

Art 12 Failure to comply with this Resolution constitutes a health violation, subjecting offenders to the penalties of Law nº 9.294, of July 2, 1996, and Law nº 6.437, of August 20, 1977, and other applicable sanctions, without impairment to such civil, administrative and criminal liability as may be apply.

Art 13 This Resolution shall enter into force on May 25, 2018.

§1 The placement of the graphic composition of warnings in the central part of the display racks or cases, as established in the sole paragraph of Art. 6, shall enter into force on May 25, 2019.

§2 Art. 7 shall enter into force on May 25, 2020.

§3 Any display racks or cases that are not in compliance with this Resolution after the time periods established in this article, must be removed from points of sale and retrieved by the responsible company.

JARBAS BARBOSA DA SILVA JR.



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ANNEX I

STANDARD HEALTH WARNING

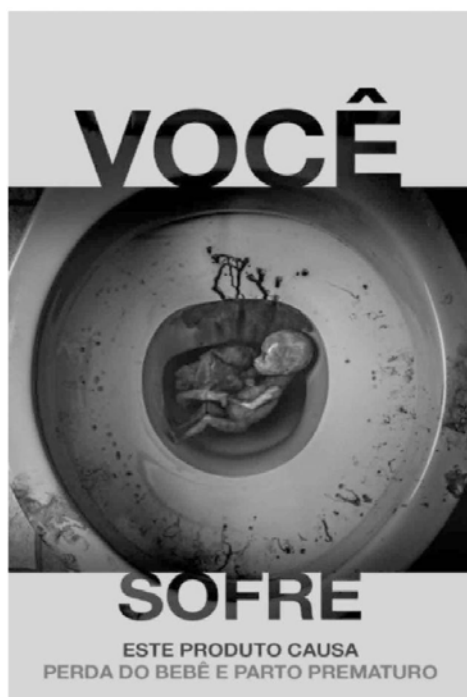
"YOU'RE GETTING OLD. THIS PRODUCT CAUSES PREMATURE AGING"





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**"YOU SUFFER. THIS PRODUCT CAUSES MISCARRIAGE AND PREMATURE
BIRTH"**





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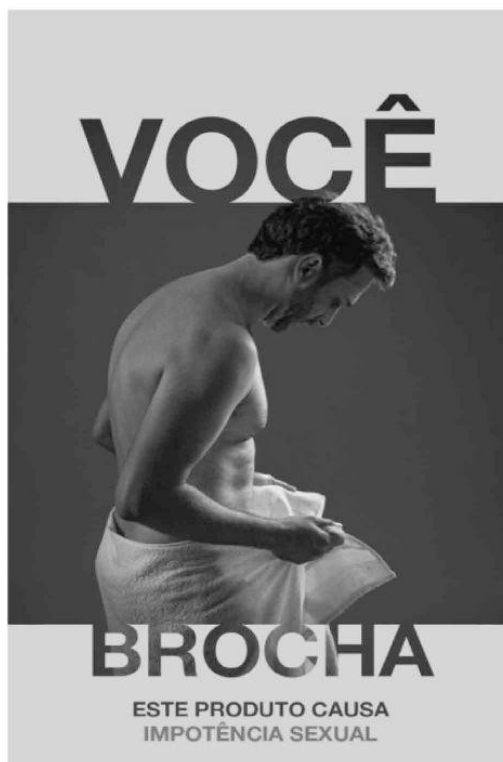
"YOU DIE. THIS PRODUCT CAUSES EMPHYSEMA, LUNG CANCER AND DEATH"





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"YOU FAIL IN BED. THIS PRODUCT CAUSES SEXUAL IMPOTENCE"





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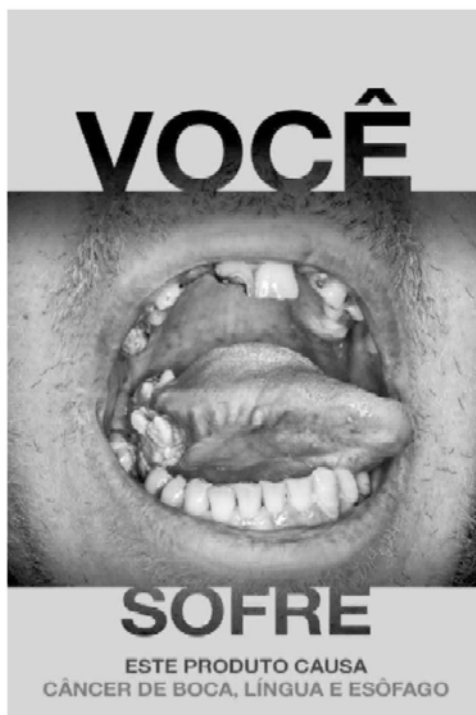
"YOU GET SICK. THIS PRODUCT CAUSES THROMBOSIS AND GANGRENE"





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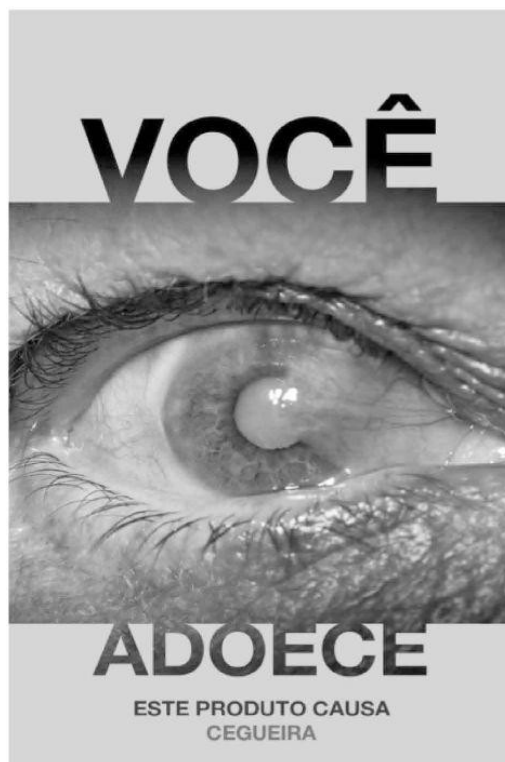
**"YOU SUFFER. THIS PRODUCT CAUSES MOUTH, TONGUE AND
ESOPHAGEAL CANCER"**





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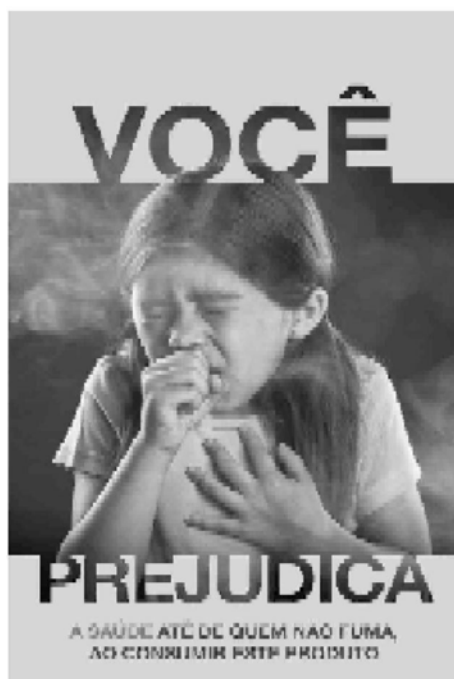
"YOU GET SICK. THIS PRODUCT CAUSES BLINDNESS"





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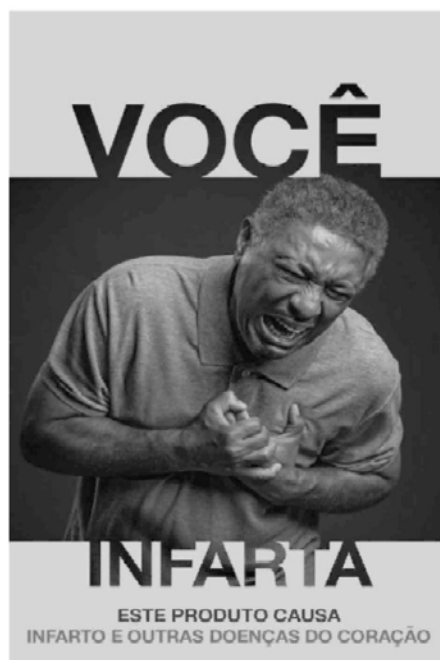
**"YOU EVEN HARM THE HEALTH OF PEOPLE WHO DON'T SMOKE
WHEN YOU CONSUME THIS PRODUCT"**





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"YOU SUFFER HEART FAILURE. THIS PRODUCT CAUSES HEART ATTACKS AND
OTHER HEART DISEASE"





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**ANNEX II
(Republished in DOU nº 19, of January 26, 2018)**

**HEALTH WARNING
DANGER: TOXIC PRODUCT**

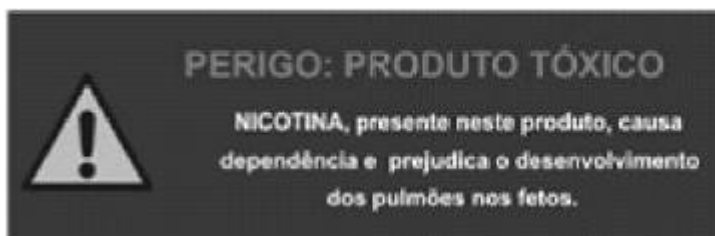
Health warning to be used with the standard health warning
"YOU'RE GETTING OLD. THIS PRODUCT CAUSES PREMATURE AGING"



DANGER: TOXIC PRODUCT

BENZENE, present in this product and also in
gasoline, causes leukemia and other kinds of cancer

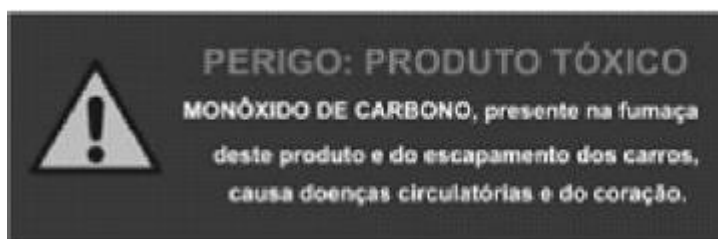
Lateral health warning to be used with the standard health warning
"YOU SUFFER THIS PRODUCT CAUSES MISCARRIAGE AND PREMATURE
BIRTH"



DANGER: TOXIC PRODUCT

NICOTINE, present in this product, causes addiction and impairs fetal lung development

Lateral health warning to be used with the standard health warning
"YOU FAIL IN BED. THIS PRODUCT CAUSES SEXUAL IMPOTENCE"



DANGER: TOXIC PRODUCT

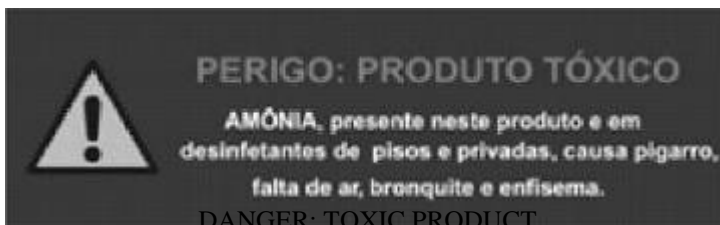
CARBON MONOXIDE, present in the smoke of this product and in car exhaust,
causes circulatory and heart disease

This text does not replace the one(s) published in the *Diário Oficial da União*.



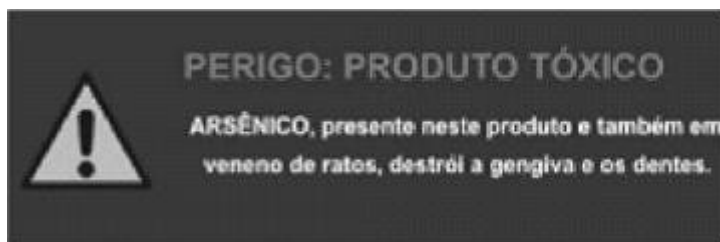
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Lateral health warning to be used with the standard health warning
"YOU DIE. THIS PRODUCT CAUSES EMPHYSEMA, LUNG CANCER AND DEATH"



AMMONIA, present in this product and in floor and toilet disinfectants,
causes coughing, shortness of breath, bronchitis and emphysema

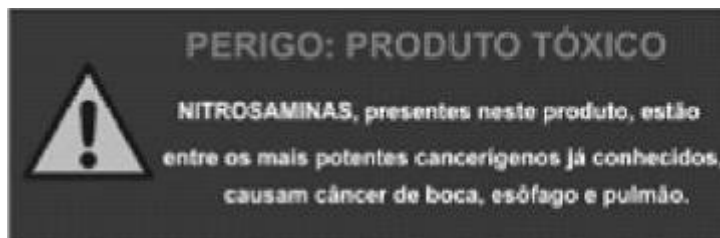
Lateral health warning to be used with the standard health warning "YOU SUFFER.
THIS PRODUCT CAUSES MOUTH, TONGUE AND ESOPHAGEAL CANCER"



DANGER: TOXIC PRODUCT

ARSENIC, present in this product, and also in rat poison,
destroys your gums and teeth

Lateral health warning to be used with the standard health warning
"YOU GET SICK. THIS PRODUCT CAUSES BLINDNESS"



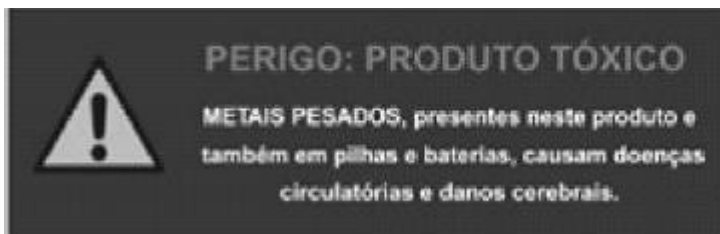
DANGER: TOXIC PRODUCT

NITROSAMINES, present in this product, are among the most powerful carcinogens ever known,
and cause cancer of the mouth, esophagus and lung.



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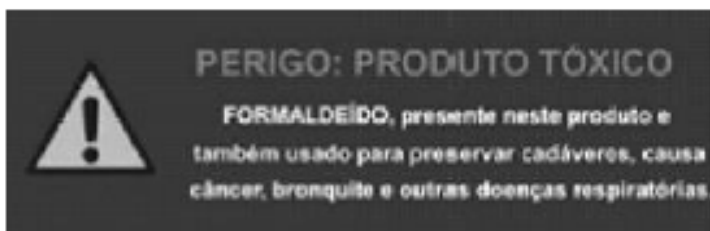
Lateral health warning to be used with the standard health warning
"YOU GET SICK. THIS PRODUCT CAUSES THROMBOSIS AND GANGRENE"



DANGER: TOXIC PRODUCT

HEAVY METALS, present in this product and also in batteries,
cause circulatory diseases and brain damage

Lateral health warning to be used with the standard health warning
"YOU EVEN HARM THE HEALTH OF PEOPLE WHO DON'T SMOKE WHEN YOU
CONSUME THIS PRODUCT"



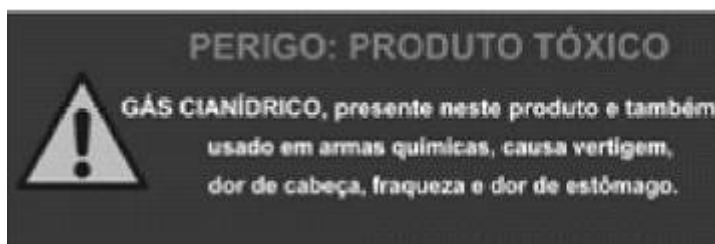
DANGER: TOXIC PRODUCT

FORMALDEHYDE, present in this product, and also used to preserve cadavers,
causes cancer, bronchitis and other respiratory diseases.



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Lateral health warning to be used with the standard health warning
"YOU SUFFER HEART FAILURE. THIS PRODUCT CAUSES HEART ATTACKS
AND OTHER HEART DISEASE"



DANGER: TOXIC PRODUCT

CYANHYDRIC GAS, present in this product, and also used in chemical weapons,
causes dizziness, headache, weakness and stomach ache.

ANNEX III

**MESSAGE OF PROHIBITION OF SALE TO MINORS UNDER THE AGE OF
EIGHTEEN**



[SALE PROHIBITED TO MINORS UNDER 18 YEARS OF AGE]



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ANNEX IV

GRAPHIC COMPOSITION FOR SINGLE PIECE ON DISPLAY CASE

Standard Health Warning (70%)	Health Warning (25%)
	Message about sale to minors under 18 (5%)

(*) 'Republished' because the text originally came out in DOU nº 240, of December 15, 2017, Section 1, page 180, without the texts in the annexes.