



**Ministry of Health - MH
National Health Surveillance Agency - ANVISA**

RESOLUTION OF THE JOINT BOARD OF DIRECTORS – RDC No. 195 OF DECEMBER 14, 2017

(Published in DOU No. 240, of December 15, 2017)

Regulations concerning packaging and health warnings for smoking products derived from tobacco.

The Joint Board of Directors of the National Health Surveillance Agency, using the powers conferred on it by Article 15, III and IV, along with Article 7, III and IV of Law No. 9,782 of January 26, 1999, Article 53, V, Paragraphs 1 and 3 of the bylaws approved in accordance with Appendix I of the Resolution of the Joint Board of Directors (RDC No. 61 of February 3, 2016), resolves to adopt the following Resolution of the Joint Board of Directors, as considered in a meeting held on October 31, 2017, and I, as Director/President, order its publication.

CHAPTER I

BASIC PROVISIONS

Article 1. Establishes the packaging requirements for all commercialized smoking products derived from tobacco.

Article 2. The primary and secondary packaging of smoking products derived from tobacco shall contain all of the health warnings about the risks arising from the use of these products, as established by Law No. 9,294/96 and Decree No. 2018/96, and their modifications, as provided for in this Resolution.

Article 3. This Resolution applies to all smoking products derived from tobacco sold domestically, both manufactured domestically and imported.

Article 4. For purposes of this Resolution, these terms are understood as:

I. Front-of-package health warning: a set of graphic elements containing written health warning messages, accompanied by the Ministry of Health consumer feedback seal, printed on the front outside panel of the packaging of smoking products derived from tobacco, as provided for in Appendix II of this Resolution;

II. Side panel health warning: a set of graphic elements containing written health warning messages printed on one of the outside side panels of the packaging of smoking products derived from tobacco, as provided for in Appendix III of this Resolution;

III. Standard health warning: a set of graphic elements containing written health warning messages, accompanied by an image printed on the outside back panel of the packaging of smoking products derived from tobacco, as provided for in Appendix I of this Resolution.



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

IV. Packaging: wrapping, enclosure or any kind of packing intended to contain smoking products derived from tobacco, with the following classification:

a) Primary packaging: packaging that covers the smoking product derived from tobacco and intended for the final consumer;

b) Secondary packaging: outside packaging of the product that contains more than one primary package, whether intended for the final consumer or not;

c) Tertiary packaging: outside product packaging that contains more than one package, and not intended for the final consumer.

V. Standard packaging: primary or secondary packaging of smoking products derived from tobacco, containing six (6) panels;

VI. Smoking product: a manufactured product, whether derived from tobacco or not, that contains leaves, extracts of leaves or other plant parts in its composition;

VII. Smoking product derived from tobacco: any manufactured product that contains tobacco in its composition;

VIII. Visual identity: the set of graphic elements that visually represents the product in a systematic way, such as images, texts, typography, color patterns, and the arrangement of elements;

IX. Name of the smoking product: name, whether accompanied or not by any descriptor, such as a word, number or package color applied to the product packaging that will be recognized as a way of distinguishing the product from others of the same type;

X. Front panel or view: the larger outside panel of the packaging that contains the name of the smoking product;

XI. Back panel or view: the larger outside panel of the packaging opposite the front-of-package panel or view.

CHAPTER II

PACKAGING

Section I

General Provisions

Article 5. It is mandatory that the primary and secondary packaging of all smoking products derived from tobacco and intended for sale in the domestic market show the following information:

I. Product name;

II. Manufacturer data: manufacturer name; corporate tax number (CNPJ), manufacturer contact, and product origin;



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

III. Importer data: name of the importer, corporate tax number (CNPJ), importer contact, and product origin;

IV. Type of product

V. Manufacture date

VI. Lot number

VII. Quantity of product in the packaging

VIII. Ingredients: type of tobacco, or if more than one type of tobacco was used, the term “mixture of tobaccos,” and all the categories of additives used in the manufacture of the product.

Subparagraph. It is mandatory that items II to VIII appear in Portuguese. They can be accompanied by information in another language.

Article 6. It is prohibited to use sound devices, words, symbols, designs or images in the primary and secondary packaging of the smoking products derived from tobacco that could:

I. Encourage immediate consumption;

II. Suggest excessive or irresponsible consumption;

III. Encourage consumption in dangerous or illegal places or situations;

IV. Suggest or convince of well-being or health;

V. Create the false impression that one brand is less harmful to health than another;

VI. Attribute calming or stimulant effects to the products, or suggest that they reduce fatigue, stress, or produce similar effects;

VI. Insinuate an increase in masculine virility or femininity or associate the idea or image of sexual success with people who smoke;

VII. Associate use of the product with cultural or sports activities, civic or religious celebrations;

VIII. Lead to erroneous conclusions as far as the characteristics and composition of the product and the health risks inherent in its use.

Section II

Health Warnings and Messages



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

Article 7. The primary and secondary packaging of all smoking products derived from tobacco must contain health warnings about the hazards arising from the use of these products and a message prohibiting sale to minors less than 18 years of age, as provided in this Resolution.

Paragraph 1. All of the health warnings and the message prohibiting sales to minors under 18 years of age must be printed on the outside part of the packaging in high resolution, legibly and highlighted clearly, consistent with the models in the appendices of this Resolution, available on the ANVISA website, without changing the proportion between its elements or its graphic parameters.

Paragraph 2. Smoking products derived from tobacco that are not cigarettes are an exception, and the printing of the health warnings and the message prohibiting sale to minors under 18 years of age may be replaced with a sticker, as long as all the requirements contained in this Resolution are observed.

Paragraph 3. The application of the sticker as provided for in Paragraph 2 of this Article, may not be placed outside the wrapping that covers the packaging, as it must still guarantee the integrity of the colors and the material with which the sticker was made, so as to prevent the sticker from being partially or completely removed.

Article 8. In standard packaging in which the upper panel has an area greater than the other panels, the upper panel will be considered as the front-of-package panel.

Article 9. It is mandatory that the standard health warning occupy 100% (one hundred percent) of the area of the outside back panel and be printed consistent with the models in Appendix I of this Resolution, which are available on the ANVISA website.

Paragraph 1. If the outside back panel of the packaging has proportions different from the models in Appendix I of this Resolution, the standard health warning shall be expanded or reduced until it occupies the largest possible area of the panel, without changing the proportions between its elements or its graphic parameters.

Paragraph 2. In cases where it is necessary to reduce the size, the standard health warnings can be reduced to 65% (sixty-five percent) of the size of the models in Appendix I of this Resolution in order to maintain legibility.

Paragraph 3. The area of the outside back panel that is not occupied by the standard health warning shall be filled with the Pantone 448C color or its equivalent on the CMYK scale, and any other printing or stickers in this area are prohibited.

Paragraph 4. The standard health warnings must be used sequentially, in a simultaneous or rotating manner, and in the latter case must be changed at most every five (5) months.



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

Paragraph 5. The manufacturer or importer must maintain registration of the packaging and distribution processes to verify the simultaneous or rotating presentation of the health warnings.

Article 10. The front-of-package health warning must occupy, at a minimum, 30% (thirty percent) of the height of the lower part of the outside front panel, the entire width of this panel, and contain three (3) elements: two (2) phrases, “THIS PRODUCT CAUSES CANCER” and “STOP SMOKING” in black letters (Pantone Process Black C scale or the equivalent in the CMYK scale), in bold, upper case, Arial font, simple spacing, and the Ministry of Health consumer feedback seal, all printed on a yellow background (Pantone 116C scale or its equivalent on the CMYK scale), as shown in the model in Appendix II of this Resolution, available on the ANVISA website.

Paragraph 1. In the case of packaging with dimensions that require that the height of the front warning be less than in the model in Appendix II of this Resolution, the three (3) elements shall be increased in size without changing the proportion between them, and the arrangement of the elements shall be changed in order to occupy the maximum area of the front warning, in a way that guarantees its legibility.

Paragraph 2. The front-of-package warning shall occupy no less than 30% (thirty percent) of the height of the area of the front panel, independent of the size of the packaging.

Article 11. It is mandatory that the side health warning panel occupy 75% (seventy-five percent) of the area of one of the larger sides and must contain two (2) elements: the phrase “Danger: Toxic Product” in red letters (Pantone 485C scale or the equivalent in the CMYK scale), in bold, upper case, Arial font, with the phrase about the hazards caused by tobacco in white letters, in bold, Arial font, all printed on a black background (Pantone Process Black C scale or the equivalent on the CMYK scale), consistent with the models in Appendix III of this Resolution, available on the ANVISA website.

Paragraph 1. If the larger outer side panel has proportions different from the models in Appendix III of this Resolution, the two (2) elements shall be increased in size without changing the proportion between them, and the arrangement of the elements shall be changed in order to occupy the maximum area of the side warning, in a way that guarantees its legibility.

Paragraph 2. The side warning shall not occupy less than 75% (seventy-five percent) of the area of one of the larger side panels, independent of the size of the packaging.

Paragraph 3. Every side health warning must be used in a way that links it to the corresponding standard health warning, as shown in Appendix III, and abide by the same simultaneous or rotating presentation of the standard warning.

Article 12. It is mandatory that the message prohibiting sale to minors under 18 years of age (“Sale Prohibited to Minors Under 18 years of age”) must occupy 25% (twenty-five percent) of the area of the same panel occupied by the side health warning, and be printed in white letters, in bold, Arial font, on a red background (Pantone 485C



Ministry of Health - MH

National Health Surveillance Agency - ANVISA

scale or the equivalent on the CMYK scale), consistent with the model in Appendix IV of this Resolution, available on the ANVISA website.

Paragraph 1. If the outer side panel of the standard packaging has proportions different from the models in Appendix IV of this Resolution, the message prohibiting sale to minors less than 18 years of age shall be expanded or reduced until it occupies 25% (twenty-five percent) of the area of the panel occupied by the side health warning.

Paragraph 2. If the largest outer side panel has proportions different from the models in Appendix IV of this Resolution, the text shall be increased in size without changing the proportions between them, and the arrangement of the words shall be changed to occupy the maximum area of this message, in a way that guarantees its legibility.

Paragraph 3. The message provided for in the caption shall not occupy less than 25% (twenty-five percent) of the area of the panel occupied by the side health warning, independent of the size of the packaging.

Section III

Exceptions

Article 13. On primary and secondary packaging that has less than six (6) panels, the following must be printed:

I - The standard health warning, consistent with the model in Appendix I of this Resolution, will occupy at a minimum 60% (sixty percent) of the area of the outside back panel or view of the packaging;

II - The front-of-package health warning, consistent with the model in Appendix II of this Resolution, shall occupy at a minimum 30% (thirty percent) of the height of the lower part of the outside front panel or view and the entire width of this panel or view;

III - The side health warning, consistent with Appendix III of this Resolution, shall occupy at a minimum 20% (twenty percent) of the area of the outside back panel or view of the packaging;

IV - The message prohibiting sale to minors under 18 years of age, consistent with the model in Appendix IV of this Resolution, shall occupy at a minimum 10% (ten percent) of the outside back panel or view of the packaging.

Paragraph 1. To comply with the provisions in Paragraph I when the outside back panel of the packaging has proportions different from the models in Appendix I of this Resolution, the standard health warning shall be expanded or reduced without changing the proportions between its elements or graphic parameters.

Paragraph 2. In cases in which the model available in Appendix I of this Resolution precludes occupying 60% (sixty percent) of the outside back panel of the label, the standard health warning shall be reduced and the remainder of the area intended for the warning shall be filled with the Pantone 448C color or its equivalent on the CMYK scale, and any other printing or sticker is prohibited in this area.



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

Paragraph 3. To comply with the provisions in Paragraph III in cases in which the model available in Appendix III of this Resolution precludes occupying 20% (twenty percent) of the outside back panel of the packaging, the two (2) elements of the side health warning, the phrase “Danger: Toxic Product” and the phrase about the hazards caused by tobacco, shall be increased in size without changing the proportion between them, and the arrangement of these elements shall be changed to occupy the maximum area of the side warning, in a way that guarantees its legibility.

Paragraph 4. To comply with the provisions in Paragraph IV, the message prohibiting sale to minors under 18 years of age shall be expanded or reduced to occupy 10% (ten percent) of the area of the outside back panel.

Paragraph 5. The arrangement of the words contained in the message prohibiting sale to minors less than 18 years of age shall be adjusted to occupy the maximum area of this warning, provided that legibility is maintained.

Paragraph 6. Packaging with less than six panels must abide by the provision in the caption in Article 9, 11 and Article 12, except the percentages for occupying and the panels where they shall be printed, which are provided for in Paragraphs I, III and IV of this article.

Paragraph 7. Packaging with less than six panels also must abide by the provisions in Paragraphs 2, 4 and 5 of Article 9, Article 10, Paragraph 3 of Article 11 and Paragraph 2 of Article 12.

Section IV

Prohibitions

Article 14. Use is prohibited of any type of wrapping, device or other feature that conceals, impedes or makes it difficult to see the health warnings and the message prohibiting sale to minors less than 18 years of age on the packaging of the products mentioned in this Resolution.

Paragraph 1. Neither the control seal of the Brazilian Federal Revenue Service (SRFBr) nor any other seal shall be superimposed on the health warnings or message prohibiting sale to minors less than 18 years of age.

Paragraph 2. There shall be no reduction or change in the graphic parameters of the health warnings or the message prohibiting sale to minors under 18 years of age in order to affix the SRFBr control seal or any other seal.

Paragraph 3. In packaging with packets, the seal indicated in Paragraph 1 shall be superimposed only on the yellow-colored area (Pantone 116C or the equivalent on the CMYK scale) of the standard health warning, without covering the text or the image.

Article 15. Regarding the packaging mentioned in this Resolution, it is prohibited to separate in any way, partial or completely, the health warnings and the message prohibiting sale to minors less than 18 years of age, even if it is only during the act of opening the packaging.



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

Subparagraph. The case of the side panel health warning and message prohibiting sale to minors under 18 years of age is an exception, and these can be split between the two sides of the opening of the package, provided that the words are not separated by folds or cutting the opening of the packaging.

Article 16. With regard to the cigarette packaging mentioned in this Resolution, it is prohibited to print the contents of tar, nicotine and carbon monoxide present in the primary or secondary stream or in the total tobacco.

Article 17. As regards the secondary packaging mentioned in this Resolution, it is prohibited:

I- To use secondary packaging that contains a unique primary packaging;

II - To use secondary packaging that does not have the same visual identity as the primary packaging.

CHAPTER III

FINAL AND TRANSITIONAL PROVISIONS

Article 18. The provisions in this rule comply with the provisions of the World Health Organization's Framework Convention on Tobacco Control, adopted by the member countries of the World Health Organization on May 21, 2003, signed by Brazil on June 16, 2003, promulgated by Decree No. 5,658 of January 2, 2006, and observing the Guidelines for its implementation, adopted by the Conference of the Parties.

Article 19. Manufacturers and importers are allowed to make packaging of smoking products derived from tobacco available to retailers, in compliance with the decisions contained in this Resolution, even before they take effect.

Article 20. After this Resolution takes effect, packaging of smoking products derived from tobacco that are not in compliance with this Resolution, cannot be produced, distributed, exhibited for sale or marketed, and shall be collected by the company holding the registration.

Article 21. The following resolutions of the Joint Board of Directors are hereby repealed: RDC No. 335, of November 21, 2003; RDC No. 168, of July 7, 2004; RDC No. 10, of February 15, 2007; RDC No. 30, of May 23, 2013; RDC No. 43, of September 3, 2013, and RDC No. 14, of April 10, 2015.

Article 22. Not complying with this Resolution constitutes a health infraction subjecting the violators to penalties under Laws No. 9,294 of July 2, 1996 and No. 6,437 of August 20, 1977, and other applicable sanctions, without prejudice to the applicable civil, administrative and penal liabilities.

Article 23. This Resolution takes effect as of May 25, 2018.

JARBAS BARBOSA DA SILVA, JR.



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

APPENDIX I

Health Warning Model

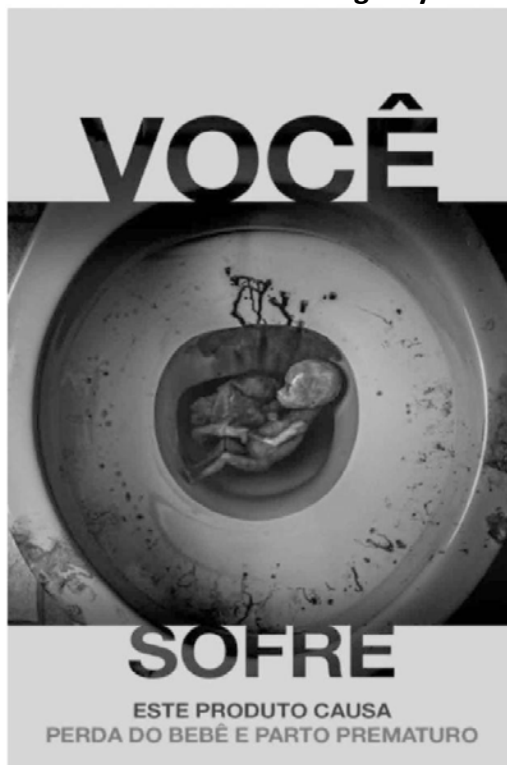
“YOU AGE. THIS PRODUCT CAUSES PREMATURE AGING”



[YOU AGE. THIS PRODUCT CAUSES PREMATURE AGING]



Ministry of Health - MH
National Health Surveillance Agency - ANVISA



[YOU SUFFER. THIS PRODUCT CAUSES MISCARRIAGES AND PREMATURE BIRTHS]



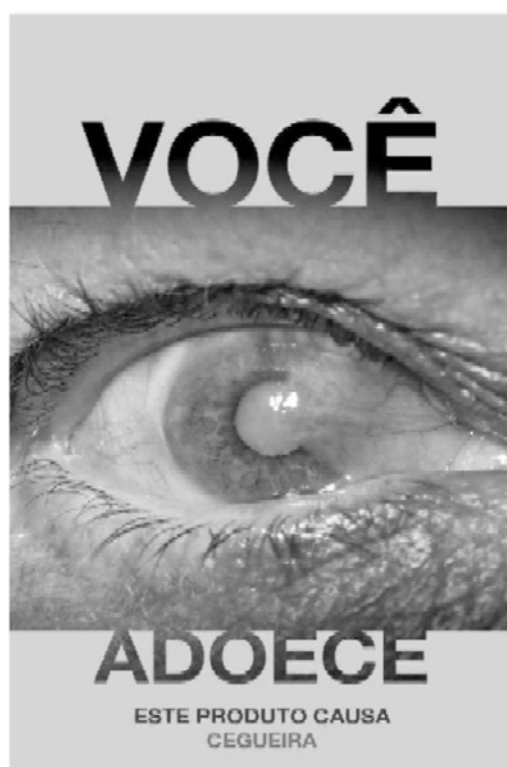
[YOU DIE. THIS PRODUCT CAUSES EMPHYSEMA, LUNG CANCER AND DEATH]



Ministry of Health - MH
National Health Surveillance Agency - ANVISA



[YOU BECOME ILL. THIS PRODUCT CAUSES THROMBOSIS AND GANGRENE]



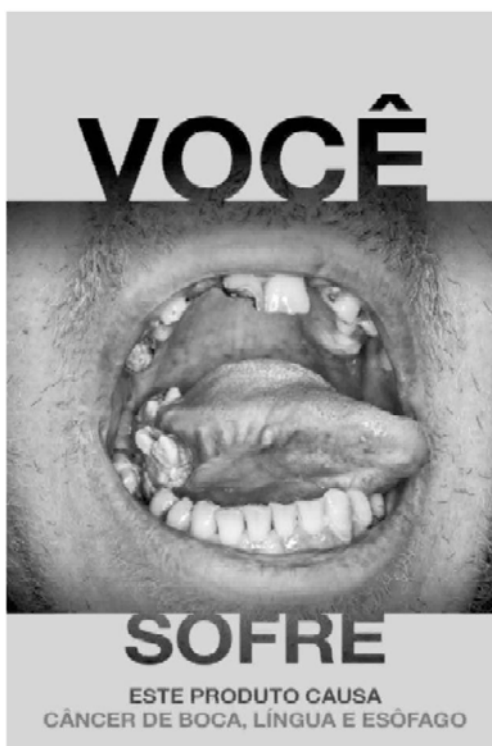
[YOU BECOME ILL. THIS PRODUCT CAUSES BLINDESS]



Ministry of Health - MH
National Health Surveillance Agency - ANVISA



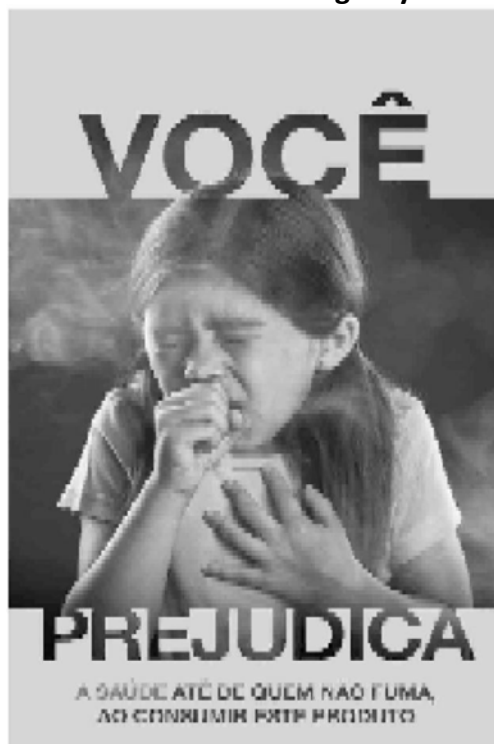
[YOU LOSE YOUR ERECTION. THIS PRODUCT CAUSES SEXUAL IMPOTENCE]



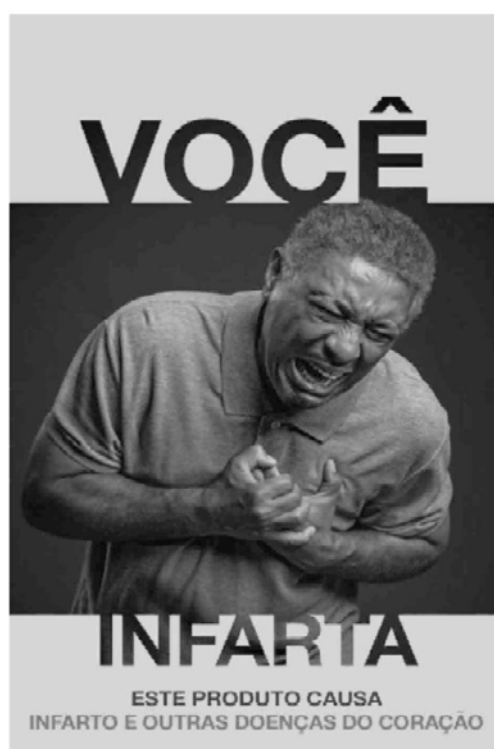
[YOU SUFFER. THIS PRODUCT CAUSES CANCER OF THE MOUTH, TONGUE
AND ESOPHAGUS]



Ministry of Health - MH
National Health Surveillance Agency - ANVISA



[IN CONSUMING THIS PRODUCT, YOU HARM THE HEALTH OF EVEN THOSE WHO DON'T SMOKE]



[YOU HAVE A HEART ATTACK. THIS PRODUCT CAUSES HEART ATTACKS AND OTHER HEART DISEASES]



**Ministry of Health - MH
National Health Surveillance Agency - ANVISA**

APPENDIX II

**Front-of-Package Health
Warning**



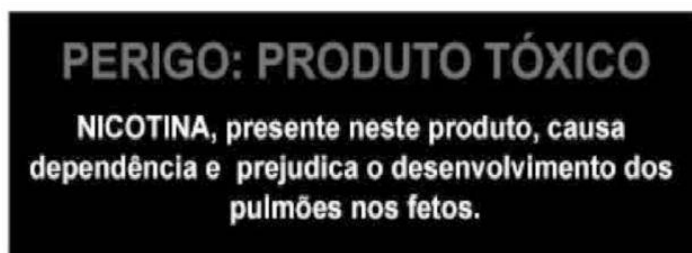
[THIS PRODUCT CAUSES CANCER. STOP SMOKING. Call Health Line 136.
Ombudsman's Office of the SUS (Brazilian public health system) www.saude.gov.br]

APPENDIX III

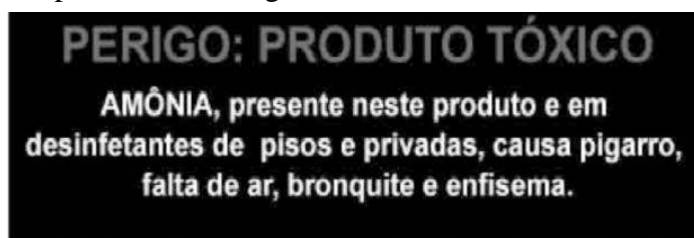
Side Panel Health Warning



[DANGER: TOXIC PRODUCT. BENZENE, present is this product and also in gasoline, causes leukemia and other types of cancer.]



[DANGER: TOXIC PRODUCT. NICOTINE, present in this product, causes addiction and harms the development of the lungs of fetuses.]



[DANGER: TOXIC PRODUCT. AMMONIA, present in this product and in floor and toilet disinfectants, causes phlegm, shortness of breath, bronchitis and emphysema.]



Ministry of Health - MH
National Health Surveillance Agency - ANVISA

PERIGO: PRODUTO TÓXICO
MONÓXIDO DE CARBONO, presente na fumaça deste produto e do escapamento dos carros, causa doenças circulatórias e do coração.

[DANGER: TOXIC PRODUCT. CARBON MONOXIDE, present in smoking this product and in car exhaust, cause circulatory and heart diseases.]

PERIGO: PRODUTO TÓXICO
METAIS PESADOS, presentes neste produto e também em pilhas e baterias, causam doenças circulatórias e danos cerebrais.

[DANGER: TOXIC PRODUCT. HEAVY METALS, present in this product and also in batteries, causes circulatory diseases and brain damage.]

PERIGO: PRODUTO TÓXICO
ARSÊNICO, presente neste produto e também em veneno de ratos, destrói a gengiva e os dentes.

[DANGER: TOXIC PRODUCT. ARSENIC, present in this product and also in rate poison, destroys the gums and teeth.]

PERIGO: PRODUTO TÓXICO
NITROSAMINAS, presentes neste produto, estão entre os mais potentes cancerígenos já conhecidos, causam câncer de boca, esôfago e pulmão.

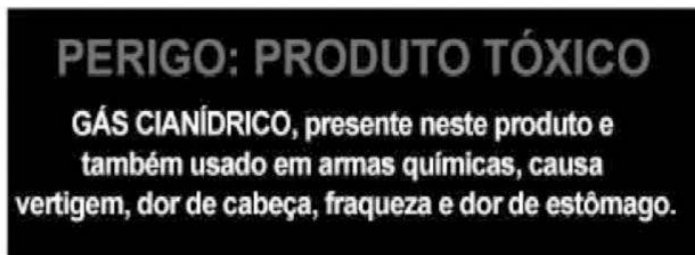
[DANGER: TOXIC PRODUCT. NITROSAMINES, present in this product, are among the most potent carcinogens known, and cause cancer of the mouth, esophagus and lungs.]

PERIGO: PRODUTO TÓXICO
FORMALDEÍDO, presente neste produto e também usado para preservar cadáveres, causa câncer, bronquite e outras doenças respiratórias.

[DANGER: TOXIC PRODUCT. FORMALDEHYDE, present in this product and also used to preserve cadavers, causes cancer, bronchitis and other respiratory diseases.]



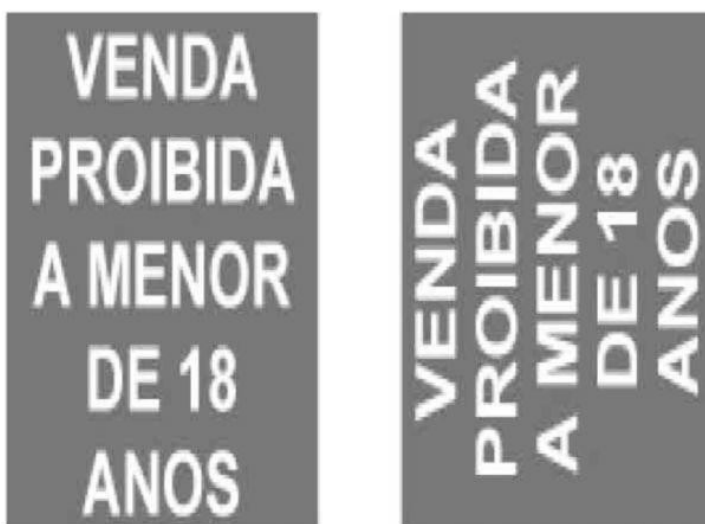
**Ministry of Health - MH
National Health Surveillance Agency - ANVISA**



[DANGER: TOXIC PRODUCT. CYANIDE GAS, present in this product and also used in chemical weapons, causes vertigo, headaches, weakness and stomach pain.]

APPENDIX IV

Message Prohibiting Sale to Minors Less Than 18 years of age



SALE PROHIBITED TO MINORS LESS THAN 18 YEARS OF AGE