

COLLEGIATE BOARD RESOLUTION – RDC NO. 136 OF 8 FEBRUARY 2017

Establishes the requirements for mandatory declaration indicating the presence of lactose on food labels.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and item V, paragraphs 1 and 3 of Article 53 of the Internal Regulation approved in the terms of Annex I of Collegiate Board Resolution – RDC no. 61 of 3 February 2016, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 31 January 2017, and I, Deputy Director-President, determine its publication.

Article 1. This Resolution establishes the requirements for mandatory declaration indicating the presence of lactose on food labels, regulating the caption of Article 19-A of Decree-Law no. 986 of 21 October 1969, which institutes basic regulations on foods.

Article 2. This Resolution applies to prepackaged food, including beverages, ingredients, food additives, and processing agents, as well as those intended exclusively for industrial processing or food services.

Paragraph 1. In a complementary way, this Resolution applies to Resolution RDC no. 259 of 20 September 2002, which approves the technical regulation for the labelling of packaged foods, and its updates.

Paragraph 2. This Resolution does not apply to the following products:

I – packaged foods that are prepared or fractioned in food services and commercialized at the establishment itself;

II – foods packaged at the points of sale at the consumer's request;

III – foods commercialized without packages; and

IV – foods for lactose-restricted diets.

Article 3. The declaration indicating the presence of lactose is mandatory for foods, including beverages, ingredients, food additives, and processing agents, that contain lactose in a quantity higher than 100 (one hundred) milligrams per 100 (one hundred) grams or milliliters of the food as displayed for sale.

Paragraph 1. In the case of infant formulas intended for specific dietary therapy needs and follow-on formulas for infants and small children intended for specific dietary therapy needs, the declaration is mandatory when the product contains lactose in a quantity higher than 10 (ten) milligrams per 100 (one hundred) kilocalories, considering the product ready to eat, in accordance with the manufacturer's package instructions.

Paragraph 2. In the case of formulas for enteral nutrition, the declaration is mandatory when the product contains lactose in a quantity higher than or equal to 25 (twenty five) milligrams per 100 (one hundred) kilocalories, considering the product ready to eat, in accordance with the manufacturer's package instructions.

Article 4. The food labels referred to in Article 3 must include the declaration “Contains lactose” immediately after or below the list of ingredients, with legible characters that comply with the following requirements:

I – upper case;

II – bold;

III – color contrasting with the label background; and

IV – minimum size of 2 mm and never smaller than the font size used in the list of ingredients.

Paragraph 1. The declarations referred to in the caption of this article may not be placed in covered locations that may be removed by opening the seal or that are difficult to see, such as sealing and folding areas.

Paragraph 2. In the case of packages with main panel area equal to or smaller than 100 (one hundred) cm², the minimum size of the characters is 1 (one) mm.

Paragraph 3. For the products exclusively intended for industrial processing or food services, the information required in the caption of this article may be provided, as an alternative, in the documents that accompany the product.

Article 5. Failure to comply with the provisions contained in this Resolution shall be considered an infraction of health regulations, pursuant to Law No. 6,437 of 20 August 1977 and its updates, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 6. This Resolution comes into force 12 (twelve) months after its publication.

Paragraph 1. Adequacy of the products to the provisions in this Resolution may be accomplished before the end of the period established in the caption of this article, as long as such provisions are fully complied with.

Paragraph 2. The products exclusively intended for industrial processing or food services must be adequate to the provisions in this Resolution from the date it comes into force.

Paragraph 3. The products intended for the final consumer must be adequate to the provisions in this Resolution in a period of 12 (twelve) months, counting from the date it comes into force.

Paragraph 4. The products manufactured by the end of their respective adequacy periods established in Paragraphs 2 and 3 may be commercialized until their expiry date.

JOSÉ CARLOS MAGALHÃES DA SILVA MOUTINHO

Deputy Director-President

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