

COLLEGIATE BOARD RESOLUTION – RDC ANVISA No. 963 OF 20 FEBRUARY 2025

Amends Collegiate Board Resolution – RDC No. 326 of 3 December 2019, which establishes the positive list of additives for use in the production of plastic materials and polymeric coatings in contact with food.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraphs 1 and 3 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 19 February 2025, and I, Acting Director-President, determine its publication.

Article 1. This Resolution amends Collegiate Board Resolution – RDC No. 326 of 3 December 2019, published in the Federal Official Gazette No. 234 of 4 December 2019, Section 1, page 95.

Sole paragraph. This Resolution incorporates GMC/MERCOSUR Resolution No. 22 of 11 September 2024 into the Brazilian legal system.

Article 2. The positive list of additives with restrictions on use and specifications contained in Table 1 of the Annex to Collegiate Board Resolution – RDC No. 326 of 3 December 2019 shall be in force with the addition of the substances listed in the Annex to this Resolution.

Article 3. This Resolution shall come into force on the date of its publication.

RÔMISON RODRIGUES MOTA

Acting Director-President

ANNEX

INCLUSIONS IN TABLE 1, WHICH PROVIDES THE POSITIVE LIST OF ADDITIVES WITH RESTRICTIONS ON USE AND SPECIFICATIONS.

Subst. MCA No.	Ref. No.	CAS No.	Substance designation	FCG applicable (yes/no)	Restrictions and specifications
M91	-	-	Silver-magnesium-sodium-boron phosphate (silver glass)	No	<p>For use as an antimicrobial agent only.</p> <p>Do not exceed 2.25% (w/w) of the substance in the finished product.</p> <p>The silver content cannot exceed 1.77% (w/w).</p> <p>LME(T) = 0.05 mg/kg (expressed as silver).</p> <p>LME(T) = 6 mg/kg (expressed as boron).</p>
M92	-	100-37-8	Diethylaminoethanol	No	<p>For use only in coatings or as a polymerization aid in plastics.</p> <p>ND (LD = 0.05 mg/kg)</p>