

# Capilene<sup>®</sup> CE 85 B

## Polypropylene

### General Statement on Compliance with Food Contact Regulations

#### Food contact – European Union

This product complies with the relevant requirements of Regulation 1935/2004/EC on materials and articles intended to come into contact with food, applicable to plastic raw materials.

This product complies with the relevant requirements of Regulation 2023/2006/EC on good manufacturing practice (GMP) for materials and articles intended to come into contact with food, applicable to plastic raw materials.

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM), on plastic materials and articles intended to come into contact with food, applicable to plastic raw materials and subsequent amendments up to and including 2023/1627.

The monomers and additives used to manufacture this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

This product contains one or more ingredients which are subject to a restriction, i.e. a specific migration limit (SML). The identity of substances with a restriction can be disclosed for testing purposes, upon special request and under maintaining secrecy.

Dual use additives may be used in the formulation of the above mentioned product. The identity of those substances can be disclosed upon special request and under maintaining secrecy.

Regulation 10/2011/EC specifies 10 mg/dm<sup>2</sup> as the maximum overall migration from finished plastic food contact articles. The migration should be measured using the actual foodstuff or the appropriate food simulants at the real time/temperature conditions of use, according to the rules specified in Regulation 10/2011/EC and subsequent amendments.

Theoretic calculation or experimental tests of overall migration performed on the above-mentioned product or on a representative material, covering long term storage at room temperature and below, including heating up to 70°C for 2 hours or up to 100°C for 15 minutes, with food simulants A, B and D2 have shown that overall migration limit of 60 mg/kg



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food was not exceeded (single use, 100% polymer used, thickness up to 250 µm, applying a surface to volume ratio of 6 dm<sup>2</sup>/kg food).

It is the responsibility of the manufacturer of the finished plastic food contact article to check and confirm that the final article meets both the technical and regulatory requirements of the application.

In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

Any potential health risk in the final article should be assessed by the manufacturer in accordance with internationally recognized scientific principles on risk assessment.

### Food contact – US Food and Drug Administration (FDA)

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.1a.

This product may contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information, these substances used in this product meet the requirements of their respective FDA regulations, FCNs, and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, excluding cooking, listed under conditions of use C through H in 21 CFR 176.170(c), Table<sup>(#)</sup> 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table<sup>(#)</sup> 1. The uses mentioned herein are subject to good manufacturing practice and any limitations that are part of the valid regulations. The regulation should be consulted for complete details.

(#) These tables can be found on the FDA website:

<http://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/foodtypesconditionsuse/cm109358.htm>

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