



## REGULATORY DATA SHEET

# **BC11**

FLEXIBLE PACKAGING

05/26 REVISION



## Regulatory Data Sheet

# BC11

## FLEXIBLE PACKAGING

### INTRODUCTION

To Whom It May Concern:

This document contains information regarding the regulatory status of Okeanos product BC11. Okeanos has relied upon the representations of third parties including vendors, suppliers, and manufacturing partners in the preparation of this document. The information below is organized according to Okeanos' manufacturing partner. For the avoidance of doubt, the information corresponding to such manufacturing partner applies solely to that individual manufacturing partner. The information in this document is provided in good faith without warranty, representation, inducement, or license of any kind.

If you have any questions regarding the regulatory statements made in this document, or if you need additional information relating to regulatory statements, please do not hesitate to contact me.

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### FOOD & DRUG ADMINISTRATION

**BR01:** The ingredients in BC11 are compliant with FDA Title 21 CFR 176.170(c) for food contact applications, as the Polyethylene base resins in this product, when used unmodified and processed in accordance with Good Manufacturing Practices (GMP), comply with FDA requirements as a food contact substance, limited to food types I through IX listed in Table 1 under Conditions of Use C through H as described in Table 2; FDA Title 21 CFR Part 178 ("Indirect food additives: adjuvants, production aids, and sanitizers"), as all other ingredients in this product are listed under that section; FDA Title 21 CFR 184.1210 GRAS (Generally Recognized as Safe) substance classification, as all remaining ingredients fall under this designation and CONEG (Coalition of Northeastern Governors) guidelines. As incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

### EU REGULATION FOR FOOD CONTACT APPLICATIONS

**BR01:** The ingredients in BC11 are compliant with EU Regulation (EU) No 10/2011 on plastic materials and articles intended for food contact applications, including all subsequent amendments in force prior to the effective date of the regulatory data sheet, subject to the following migration limits: OML of 10 mg/dm<sup>2</sup> (Article 12); SML for Hexene-1 (CAS: 592-41-6) of 3 mg/kg; SML(T) for Zinc Oxide (CAS: 1314-13-2) of 5 mg/kg; and SML for Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate (CAS: 2082-79-3) of 6 mg/kg of food or food simulant; EU Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food; EU Good Manufacturing Practices Regulation (EC) No 2023/2006, allowing use in EU countries for the manufacturing of plastic materials and articles for food contact applications; European Directive 94/62/EC on packaging and packaging waste (Article 11), as incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total and EU REACH Regulation (EC) No 1907/2006, as the product is not manufactured or formulated with any Substances of Very High Concern (SVHCs) on the candidate list as of the effective date of the regulatory data sheet.

## LATIN AMERICA MERCOSUR FOOD CONTACT STATUS

**BR01:** The ingredients in BC11 are compliant with MERCOSUR GMC Resolution No. 56/92 (Positive List substances and annexes for food contact), subject to an OML of 8 mg/dm<sup>2</sup> or 50 mg/kg of food or food simulant.

The ingredients in BC11 are compliant with MERCOSUR GMC Resolution No. 39/19 (governing framework for food contact by plastics), with all intentionally added substances on the Positive List and within established limits; MERCOSUR GMC Resolution No. 02/12 (colorants for food contact) and MERCOSUR GMC Resolution No. 15/10 (monomers and starting substances for food contact), subject to the following specific migration limits applicable across all Mercosur resolutions:

- SML: Hexene-1 (CAS: 592-41-6) = 3 mg/kg of food or food simulant
- SML(T): Zinc Oxide (CAS: 1314-13-2) = 5 mg/kg of food or food simulant
- SML: Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate (CAS: 2082-79-3) = 6 mg/kg of food or food simulant

## BRAZIL ANVISA FOOD CONTACT STATUS

**BR01:** The ingredients in BC11 are compliant with ANVISA Resolution No. 105/1999 (Positive List for food contact materials); ANVISA Resolution No. 91/2001 (substances approved for food contact); ANVISA Resolution No. 326/2019 (additives, metal limits, phthalate-free requirements, solvents, and primary aromatic amines); ANVISA Resolution No. 52/2010 (colorants for food contact); ANVISA Resolution No. 56/2012 (monomers and starting substances for food contact), subject to the following migration limits applicable across all ANVISA resolutions:

- OML: 10 mg/dm<sup>2</sup> or 60 mg/kg of food or food simulant (RDC 589/21)
- SML: Hexene-1 (CAS: 592-41-6) = 3 mg/kg of food or food simulant
- SML(T): Zinc Oxide (CAS: 1314-13-2) = 5 mg/kg of food or food simulant
- SML: Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate (CAS: 2082-79-3) = 6 mg/kg of food or food simulant

## MATERIALS FROM GENETICALLY MODIFIED ORGANISMS (EU REGULATIONS (EC) 1829/2003 & 1830/2003)

**BR01:** The ingredients in BC11 are compliant with EU Regulations (EC) 1829/2003 and 1830/2003 on materials derived from genetically modified organisms, as to the best of the manufacturer's knowledge no raw materials or additives have been derived from genetically modified organisms, based on information provided by additive suppliers.

## FOOD ALLERGENS (RDC ANVISA 26/2015, REGULATION (EU) 1169/2011, FALCPA 2004 (US))

**BR01:** The ingredients in BC11 are compliant with RDC ANVISA 727/2022, EU Regulation 1169/2011, and FALCPA 2004 (US), as no raw materials or additives have their origin in peanuts, soybeans, milk, eggs, fish, shellfish (mollusks), crustaceans, tree nuts, mustard, celery, sesame, sunflowers, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives.

## CALIFORNIA PROPOSITION 65

**BR01:** The ingredients in BC11 are compliant with California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act), as the product does not contain any of the listed substances known to the State of California to cause cancer, birth defects, or other reproductive harm at levels that would require a warning under the statute as of the effective date of the regulatory data sheet.



## LEGAL DISCLAIMER

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This product is not intended for the use in medical applications and should not be used in any such applications

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