

REGULATORY DATA SHEET

BC05

BOARD SUBSTRATE HDPE

11/26 REVISION

Regulatory Data Sheet

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REGULATORY STATEMENT

To Whom It May Concern:
This document contains information regarding the regulatory status of Okeanos product BC05. 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

EC01: The ingredients in BC05 are compliant with the following legislations: FDA 21 CFR 174.500, 177.1520, 175.300 and 175.320, 178.2010 and 178.3297.

IN01: The ingredients in BC05 are compliant with the following legislations: FDA Title 21 Sections 176 and 177.

EU REGULATION FOR FOOD CONTACT APPLICATIONS

EC01: The ingredients in BC05 are compliant with the EU Resolution AP (89) I, corresponding to the use of colorants in plastic materials that will be in contact with food; the European Commission Regulation (EU) 10/2011; Regulation (EU) Number 1935/2004 and Regulation (EU) Number 2023/2006. The ingredients in BC05 are compliant with Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

IN01: Compliance to Commission Regulation (EU) Number 10/2011 and Regulation (EU) Number 1169/2011. The ingredients in BC05 are compliant with European Directive 94/62/EC Article 11.

REACH *(EU REGULATION (EC) NO. 1907/2006)*

EC01: BC05 complies with REACH Legislation Number 1907/2006 and is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

IN01: BC05 complies with REACH Legislation Number 1907/2006.

HEAVY METALS EU 94/62/EC & COALITION OF NORTHEASTERN GOVERNORS *(CONEG)*

EC01: The ingredients in BC05 are compliant with the CONEG (Coalition of Northeastern Governors) Regulation, USA and European Directive 94/62/EC Article 1; and the RoHS Directive (2015/863/EU), regarding heavy metal content.

IN01: The ingredients in BC05 are compliant with European Directive 94/62/EC Article 11.

LATIN AMERICA MERCOSUR FOOD CONTACT STATUS

EC01: The ingredients in BC05 are compliant with the MERCOSUR GMC Resolution Number 56/92 and the MERCOSUR GMC Positive list of additives for packaging in contact with food Resolution Number 39/19.

IN01: The ingredients in BC05 are compliant with MERCOSUR GMC Resolution Number 56/92, Resolution Number 39/19, Resolution Number 02/12 and Resolution Number 15/10.

BRAZIL ANVISA FOOD CONTACT STATUS

IN01: Complies with Brazil ANVISA RDC Resolution Number 326/2019.

MATERIALS FROM GENETICALLY MODIFIED ORGANISMS *(regulations (EC) 1829/2003 & 1830/2003)*

EC01: BC05 does not contain materials from genetically modified organisms and is compliant with Regulations EU 1829/2003 and 1830/2003.

IN01: BC05 does not contain materials from genetically modified organisms and is compliant with Regulations (EC) 1829/2003 and 1830/2003.

ANIMAL DERIVED COMPONENTS (BSE/TSE)

EC01: BC05 does not contain Animal Derived Components (BSE/TSE).

IN01: Does not contain Animal Derived materials.

PLANT DERIVED COMPONENTS

EC01: BC05 does not contain plant derived components.

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

EC01: BC05 complies with US Allergens FALCPA 2004 regulation and Food Allergens Regulation (EU) Number 1169/2011.

IN01: BC05 complies with US Allergens FALCPA 2004 and does not contain fish, shellfish, milk, eggs, soy, wheat (gluten), peanuts, tree nuts or sesame seeds.

CALIFORNIA PROPOSITION 65

IN01: Does not use or intentionally add anything on the Chemicals List of Proposition 65 of the State of California and subsequent amendments, as known to the State of California to cause cancer or reproductive toxicity.

PERFLUOROALKYL SUBSTANCES (PFAS, PFOS, PFOA)

EC01: BC05 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

IN01: The formulation of BC05 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

HALAL

EC01: BC05 does not contain any risk of containing illicit substances in the composition for the consumption of Muslims and without risk of cross-contamination in the production line with these 'Haram' (illegal, prohibited) substances.

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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