

REGULATORY DATA SHEET

BC06

RIGID PACKAGING HDPE SPECIFIC TO BLOW MOLDING

11/26 REVISION

Regulatory Data Sheet

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INTRODUCTION

To Whom It May Concern:
This document contains information regarding the regulatory status of Okeanos product BC06. 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 BC06 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 BC06 are compliant with the following legislations: FDA Title 21 Sections 176 and 177.

TH01: The raw materials are formulated in compliance with applicable sections of FDA Title 21 CFR, including 21 CFR 177.1520 for polymers

TR01: FDA 21 CFR,582.1191: Substances generally recognized as safe (General Purpose Food Additives) (Calcium carbonate). FDA 21 CFR 177.1520 for plastic olefin polymers and for food contact application.

EU REGULATION FOR FOOD CONTACT APPLICATIONS

EC01: The ingredients in BC06 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.

IN01: Compliance to Commission Regulation (EU) Number 10/2011 and Regulation (EU) Number 1169/2011.

TH01: All additives and monomers used in BC06 are listed in the Union List under Regulation (EU) No. 10/2011, and Specific Migration Limits (SML) are maintained within legal boundaries.

TR01: Compliance to Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food / EU No

1169/2011: No allergen substance / It complies with the Packaging and Packaging Waste Directive 94/62/EC of the European Parliament.

EU REGULATION (EC) 1935/2004, EC 2023/2006, AND DIRECTIVE 2012/19/EU

EC01: The ingredients in BC06 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.

IN01: The ingredients in BC06 are compliant with European Directive 94/62/EC Article 11.

TR01: Complies 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.

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

EC01: BC06 complies with REACH Legislation Number 1907/2006 and is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

IN01: BC06 complies with REACH Legislation Number 1907/2006.

TH01: The product does not contain any Substances of Very High Concern (SVHC) above the 0.1% (w/w) threshold.

TR01: Chemicals specified in the Candidate List of Substances of High Importance (SVHC List), including chemicals added by the European Chemicals Agency (ECHA) to the REACH Regulation No. 1907/2006/EC on 14.06.2023, are not consciously used and are not expected to exceed the limit values.

HEAVY METAL REGULATIONS

EC01: The ingredients in BC06 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.

TH01: The product is free from heavy metals (Pb, Hg, Cd, Cr VI) and restricted flame retardants under RoHS Directive (2015/863/EU).

MERCOSUR FOOD CONTACT REGULATIONS

EC01: The ingredients in BC06 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 BC06 are compliant with MERCOSUR GMC Resolution Number 56/92, Resolution Number 39/19, Resolution Number 02/12 and Resolution Number 15/10.

TH01: Raw material in this product complies with MERCOSUR GMC Resolution No. 02/12 (Monomers/Polymers) and Resolution No. 39/19 (Additives). The product meets the requirements for Overall and Specific Migration Limits (SML) under Resolution No. 15/10 and Resolution No. 51/2010.

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: BC06 does not contain materials from genetically modified organisms and is compliant with Regulations EU 1829/2003 and 1830/2003.

IN01: BC06 does not contain materials from genetically modified organisms and is compliant with Regulations (EC) 1829/2003 and 1830/2003.

TH01: The product is free from Genetically Modified Organisms (GMO).

ANIMAL DERIVED MATERIALS

EC01: BC06 does not contain Animal Derived Components (BSE/TSE).

IN01: Does not contain Animal Derived materials and complies with BSE/TSE requirements.

TH01: The components are mineral, synthetic, or vegetable based. No animal-derived materials (BSE/TSE risk) are used in the manufacturing process.

PLANT DERIVED COMPONENTS

EC01: BC06 does not contain plant derived components.

ALLERGENS

EC01: BC06 complies with US Allergens FALCPA 2004 regulation and Food Allergens Regulation (EU) Number 1169/2011.

IN01: BC06 complies with US Allergens FALCPA 2004 and does not contain fish, shellfish, milk, eggs, soy, wheat (gluten), peanuts, tree nuts or sesame seeds.

TH01: The product does not contain fish, shellfish, milk, eggs, soy, wheat, peanuts, tree nuts, or sesame seeds (US Allergens FALCPA), and is free from allergens as per EU Regulation No. 1169/2011.

PERFLUOROALKYL SUBSTANCES *(PFAS, PFOS, PFOA)*

EC01: BC06 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

IN01: The formulation of BC06 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

TH01: This product is not manufactured with and does not contain Perfluoroalkyl and Polyfluoroalkyl substances (PFAS).

CALIFORNIA PROPOSITION 65

IN01: Does not use or intentionally add (above the applicable limits 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.

TH01: None of the substances in this product are listed on the Prop 65 list (updated as of December 2023 or newer) at concentrations requiring a warning.

HALAL

EC01: BC06 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.

TH01: The product contains no Haram substances and is processed under conditions that avoid cross-contamination.

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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