

REGULATORY DATA SHEET

BC03

THERMOFORMING & THIN PROFILES EXTRUSION PP

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 BC03. 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 Polypropylene base resin in this product, when used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, will comply with the U.S. Food and Drug Administration as a food contact substance. The use of this product in producing articles or components of articles used in contact with food is limited to types I through IX listed in Table 1, under Conditions of Use A through H, as described in Table 2 per 176.170 (c).

All other ingredients used in this product are listed in part 178 of FDA Title 21 Code of Federal Regulations, "Indirect food additives: adjuvants, production aids, and sanitizers", or are classified as GRAS substances according to the section 184.1210.

The preceding statement refers to regulatory requirements only, not to the product's physical utility. It is the responsibility of the article producer or food packager to determine that the article is suitable for its intended use.

CO01: The materials used in the manufacture of this compound are FDA (Food and Drug Administration) compliant for use in food contact applications, according to FDA 21 CFR.

EC01: The ingredients in BC03 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 BC03 are compliant with the following legislations: FDA Title 21 Sections 176 and 177.

MX04: The materials used in BC03 are recognized by the FDA for food contact applications under 21 CFR.

TH01: CFR 177.1520 for plastic olefin polymers and for food contact application. The declaration outlines the permissible conditions of use, including temperature limits, types of food contact, and any additives or substances that may be used in the manufacturing process.

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.

US02: Ingredients in BC03 are compliant to 21 CFR Food and Drugs, Sections 178.3297 Colorants for Polymers, 177.1520 Olefin Polymers and may be used as articles or components of articles intended for use in contact with foods in Table 1 and Conditions of use B-H of Table 2 of 176.170 (c).

The CFR sections should be consulted for the complete text before any conclusion is made as to the allowed regulated use. It is the responsibility of the converter or packer of the finished article to verify the article meets both the technical and regulatory requirements of the intended application and does not modify the organoleptic properties of the food.

US04: This product complies with FDA regulation 21 CFR 177.1520 (Olefin polymers), paragraphs (c)3.1a and (c)3.2a and may be used as articles or components of articles intended for use in contact with food, including use in articles used for packing or holding food during cooking.

Finished articles may contact all food types identified in Table 1 of 21 CFR 176.170(c) under Conditions of Use A through H as described in Table 2 of 21 CFR 176.170(c).

EU REGULATION FOR FOOD CONTACT APPLICATIONS

BR01: The composition of this product complies with the requirements for use in food contact applications of the European Commission Regulation (EU) No 10/2011, including any subsequent amendments that are in force prior to the effective date of this regulatory data sheet. However, the finished article must meet the following Overall Migration Limit (OML), Specific Migration Limits (SML) and Total Specific Migration Limits (SML(T)):

- OML: 10 mg/dm^2 (Article 12);
- SML: 9,9 – bis (methoxymethyl) fluorene (CAS:182121-12-6) = 0.05 mg/kg of food or food simulant;
- SML(T): Aluminium = 1 mg/kg of food or food simulant;
- SML(T): Amines, C13-15-alkyl, ethoxylated (CAS:70955-14-5) = 1.2 mg/kg of food or food simulant;
- SML: Disodium cis-endo-bicyclo (2.2.1) heptane- 2-3-dicarboxylate (CAS: 351870-33-2) = 5 mg/kg of food or food simulant.

The processing of this product follows the Good Manufacturing Practices Regulation (EC) n° 2023/2006, allowing this product to be used in the countries of the European Union for the manufacturing of plastic materials and articles to food contact applications, according to the Regulation (EC) n° 1935/2004, as amended.

It remains the responsibility of the end-user to ensure compliance of the finished articles with the abovementioned Migration Limits.

EC01: The ingredients in BC03 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 BC03 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. BC03 complies with the European Directive 94/62/EC Article 11.

MX04: BC03 complies with Commission Regulation (EU) No 10/2011 and its amendments and does not contain additives with a specific migration limit (SML). BC03 complies with Regulation (EC) No 1935/2004 and is manufactured under Good Manufacturing Practices in accordance with Regulation (EC) No 2023/2006.

TH01: Regulation (EU) No.10/2011 (and amendments) on plastic material and articles intended to come into contact with food (former Directive 220/72/EC) / Restriction of Hazardous Substances (RoHS) Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU.

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. 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.

US04: The ingredients in BC03 are compliant with EU Regulation (EU) No 10/2011 on plastic materials and articles intended to contact food, as amended by Commission Regulation 2023/1442 (16th amendment, effective February 21, 2025), with all substances authorized and restrictions observed; EU Regulation No 1935/2004 on materials and articles intended to come into contact with food; EU Regulation No 2023/2006 on good manufacturing practices for materials and articles intended to contact food; EU Regulation No 1169/2011 on food allergen labeling, as none of the regulated allergens are present; European Directive 94/62/EC on heavy metals in packaging, containing no materials outside the Positive List; EU REACH Regulation, as no Substances of Very High Concern (SVHCs) listed in REACH Annex XVII or on the Candidate List for Authorization are present; RoHS Directive 2015/863/EU on the restriction of hazardous substances and EU Regulation 1829/2003 and 1830/2003 on genetically modified organisms, as no GMO-derived materials are present or intentionally used.

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

BR01: This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet, that would require reporting under the regulation.

EC01: BC03 complies with REACH Legislation Number 1907/2006 and is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

IN01: BC03 complies with REACH Legislation Number 1907/2006.

MX04: BC03 does not contain any Substances of Very High Concern (SVHCs) under REACH Regulation (EC) No 1907/2006.

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.

US04: BC03 does not contain SVHCs in any of their products, including substances listed in REACH Annex XVII.

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

BR01: This product conforms to the Coalition of Northeastern Governors (CONEG) and the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

EC01: The ingredients in BC03 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.

MX04: BC03 complies with European Directive 94/62/EC Article 11, CONEG requirements and the RoHS Directive (2015/863/EU) regarding heavy metal content; levels do not exceed 100 ppm, should any be present.

US04: The ingredients in BC03 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.

LATIN AMERICA MERCOSUR FOOD CONTACT STATUS

BR01: This product complies with MERCOSUR GMC Resolution No. 56/92, Resolution No. 39/19, Resolution No. 02/12 and Resolution No. 15/10. However, the finished article must comply with the following Overall Migration Limit (OML), Specific Migration Limits (SML) and Total Specific Migration Limits (SML(T)): OML: 8 mg/dm^2 or 50 mg/kg of food orfood simulant (GMC 56/92); SML: 9,9 – bis (methoxymethyl) fluorene (CAS:182121-12-6) = 0.05 mg/kg of food or food simulant; SML(T): Aluminium = 1 mg/kg of food or food simulant; SML(T): Amines, C13-15-alkyl, ethoxylated (CAS:70955-14-5) = 1.2 mg/kg of food or food simulant; SML: Disodium cis-endo-bicyclo (2.2.1) heptane-2-3-dicarboxylate (CAS: 351870-33-2) = 5 mg/kg of food or food simulant. It remains the responsibility of the end-user to ensure compliance of the finished articles with the abovementioned Migration Limits.

EC01: The ingredients in BC03 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 BC03 are compliant with MERCOSUR GMC Resolution Number 56/92, Resolution Number 39/19, Resolution Number 02/12 and Resolution Number 15/10.

MX04: BC03 complies with MERCOSUR GMC Resolution No. 02/12 and Resolution No. 15/10. Compliance with MERCOSUR GMC Resolution No. 56/92 and with the Código Alimentario Argentino (Chapter V, Article 235) is the responsibility of the converter according to the final use of the article.

US04: The ingredients in BC03 are compliant with Mercosur GMC Resolution 39/19, the governing framework for food contact by plastics, with all intentionally added substances on the Positive List, within metal limits, phthalate-free, and meeting guidelines for solvents and primary aromatic amines; Mercosur GMC Resolution 56/92 (Positive List substances and annexes for food contact); Mercosur GMC Resolution 02/12 (colorants for food contact), as no colorants are intentionally used; Mercosur GMC Resolution 15/10 (monomers and starting substances for food contact), as no pigments are intentionally utilized and Argentina Food Safety Code (Código Alimentario Argentino) as it pertains to food contact suitability, consistent with Mercosur standards and Positive List requirements.

BRAZIL ANVISA FOOD CONTACT STATUS

BR01: This product complies with ANVISA Resolution No. 105/1999, Resolution No. 91/2001, Resolution No. 326/2019, Resolution No. 52/2010 and Resolution No. 56/2012.

However, the finished article must comply with the following Overall Migration Limit (OML), Specific Migration Limits (SML) and Total Specific Migration Limits (SML(T)):

- OML: 10 mg/dm^2 or 60 mg/kg of food or food simulant (RDC 589/21);
- SML: 9,9 – bis (methoxymethyl) fluorene (CAS:182121-12-6) = 0.05 mg/kg of food or food simulant;
- SML(T): Aluminium = 1 mg/kg of food or food simulant; SML(T): Amines, C13-15-alkyl, ethoxylated (CAS:70955-14-5) = 1.2 mg/kg of food or food simulant;
- SML: Disodium cis-endo-bicyclo (2.2.1) heptane- 2-3-dicarboxylate (CAS: 351870-33-2) = 5 mg/kg of food or food simulant.

It remains the responsibility of the end-user to ensure compliance of the finished articles with the abovementioned Migration Limits.

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

MX04: BC03 complies with Brazil ANVISA RDC Resolution No. 56/2012. Compliance with ANVISA RDC Resolutions 105/1999, 91/2011, 51/2010 and 727/2022 is the responsibility of the converter according to the final use of the article.

US04: The ingredients in BC03 are compliant with Brazil ANVISA RDC Resolution 105/1999 (Positive List for food contact materials); Brazil ANVISA RDC Resolution 326/2019 (additives, metal limits, phthalate-free requirements, solvents, and primary aromatic amines); Brazil ANVISA RDC Resolution 52/2010 (colorants for food contact), as no colorants are present; Brazil ANVISA RDC Resolution 56/2012 (monomers and starting substances for food contact); Brazil ANVISA RDC Resolution 91/2011 (substances approved on the Positive List for food contact). The ingredients in BC03 are compliant with Brazil ANVISA RDC Resolution 51/2010 (Positive List substances and annexes) and Brazil ANVISA Food Allergens Regulation 26/2015, including the May 2024 update, as none of the regulated allergens are present

JAPAN FOOD CONTACT REGULATIONS

US04: The ingredients in BC03 are compliant with the Japanese Ministry of Health, Labour and Welfare (MHLW) Positive List System for food-contact materials, effective June 1, 2025, as all raw materials used in production are listed on the corresponding Positive List and no additives are intentionally incorporated.

CANADA FOOD CONTACT REGULATIONS

US04: The ingredients in BC03 are compliant with Canada Food and Drug Act, Division 23, Section B.23.001, which prohibits the sale of foods in packages that may impart harmful substances to contents, based on conformity with FDA and EU regulations governing food contact materials.

GERMAN FOOD CONTACT REGULATIONS

US04: The ingredients in BC03 are compliant with German BfR (Bundesinstitut für Risikobewertung) recommendations, specifically Section III (Polyethylene) and Section LII (Fillers), both in conformity with EU Regulation (EU) No 10/2011 for food contact applications.

CHINA FOOD CONTACT REGULATIONS

US04: The ingredients in BC03 are compliant with China GB 9685-2016 (national standard for the use of additives in food contact materials) and with GB 4806.1-2016 (general safety requirements for food contact materials and articles).

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

BR01: To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO). This is based on information from our additive suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it.

EC01: BC03 does not contain materials from genetically modified organisms and is compliant with Regulations EU 1829/2003 and 1830/2003.

IN01: BC03 does not contain materials from genetically modified organisms and is compliant with Regulations (EC) 1829/2003 and 1830/2003.

MX04: The raw materials used in BC03 do not contain ingredients derived from genetically modified organisms (Regulations (EC) 1829/2003 and 1830/2003).

US04: The ingredients in BC03 are compliant with EU Regulation 1829/2003 and 1830/2003 on genetically modified organisms, as no GMO-derived materials are present or intentionally used, as well as GMO-free requirements, as genetically modified organisms are not intentionally used.

ANIMAL DERIVED COMPONENTS *(BSE/TSE)*

BR01: This product contains additives derived from animal origin. However, this(ese) substance(s) is(are) highly processed, obtained through Transesterification, Hydrolysis or Saponification processes at temperatures higher than 140 °C for not less than 8 minutes.

EC01: BC03 does not contain Animal Derived Components (BSE/TSE).

IN01: BC03 complies with regulations concerning Animal Derived Components (BSE/TSE).

MX04: BC03 does not contain Animal Derived Components (BSE/TSE).

US04: The ingredients in BC03 are compliant with animal origin content requirements as well as USMCA manufacturing standards, as all raw materials are manufactured within the USMCA and this product does not come into contact with any animal-derived material during processing, handling, or packaging.

PLANT DERIVED COMPONENTS

BR01: This product may contain one or more substances(s) synthesized from plant extracts, i.e, hydrolysis of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.

EC01: BC03 does not contain plant derived components.

MX04: BC03 does not contain plant derived components.

US04: The ingredients in BC03 are compliant with the Lacey Act of 1900 (16 U.S.C. §§ 3371–3378), as its raw material suppliers do not directly add any plant-derived ingredients into the raw materials, and the product does not encounter any plant-derived material during manufacturing, processing, handling, or packaging. It is also compliant with plant-derived substance restrictions, as the product contains no oils, glycerin, or proteins derived from the Jatropha plant or any Jatropha extract, and with cellulose-free requirements, as the product does not contain any materials that could be described as cellulose, and cellulose is not used during any stage of the production process.

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

BR01: To the best of our knowledge, there are no raw materials, including additives, that 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. No sulfates, sulfites, or sulfur dioxide are used in the synthesis of this material. This evaluation is based on information provided by our raw materials and additives suppliers for the presence of the allergenstimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this.

EC01: BC03 complies with US Allergens FALCPA 2004 regulation and Food Allergens Regulation (EU) Number 1169/2011.

IN01: BC03 complies with US Allergens FALCPA 2004 and does not contain fish, shellfish, milk, eggs, soy, wheat (gluten), peanuts, tree nuts or sesame seeds.

MX04: BC03 does not contain allergens and complies with US Allergens FALCPA 2004, Food Allergens Regulation (EU) No 1169/2011 and Brazil ANVISA Food Allergens Regulation 26/2015.

US04: The ingredients in BC03 are compliant with the Allergen Labeling and Consumer Protection Act of 2004 (FALCPA, 21 U.S.C.), as the following allergens are not expected to be present: milk (including lactose), eggs, fish (e.g.,

, bass, flounder, cod), crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, pecans, walnuts), wheat containing gluten, peanuts, and soybeans. It is also are compliant with EU Regulation No 1169/2011 on food allergen labeling, as none of the regulated allergens are present; Brazil ANVISA Food Allergens Regulation 26/2015, including the May 2024 update, as none of the regulated allergens are present, and with extended allergen-free requirements, as the product also does not contain sesame seed, celery, sulphur dioxide and sulfites, lupin, or natural or synthetic latex.

PERFLUOROALKYL SUBSTANCES (PFAS, PFOS, PFOA)

EC01: BC03 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

IN01: The formulation of BC03 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

MX04: BC03 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

US04: The ingredients in BC03 are compliant with EPA PFAS requirements, as the product does not contain any perfluoroalkyl or polyfluoroalkyl substances (PFAS) named in the FDA CompTox Chemicals Dashboard.

HALAL

EC01: BC03 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.

MX04: BC03 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 'Haram' (illegal, prohibited) substances.

CALIFORNIA PROPOSITION 65

IN01: Regarding the presence of substances on the California Proposition 65 list (Safe Drinking Water and Toxic Enforcement Act of 1986) in this product, as set forth in the latest listing dated January 3rd, 2025 at levels equal to or greater than 10 ppb.

The following impurity may be present: • N-hexane (CAS Number 110-54-3), at levels < 0.025 ppm = 25 ppb.

This product does not contain any other of the listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute as of the effective date of this regulatory datasheet.

MX04: None of the substances on the California Proposition 65 list (December 29, 2023 update or newer) are present in BC03.

US04: The ingredients in BC03 are compliant with California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act), as none of the substances listed as potentially causing cancer, birth defects, or other reproductive harm — as of the December 29, 2023 update — are expected to be present, and none are intentionally used.

NITRITES DECLARATION

BR01: We declare that the presence of nitrites is not expected in the raw materials that make up the formulations of the following products: BC03.

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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