



REGULATORY DATA SHEET

BC01

FLEXIBLE PACKAGING HDPE

05/26 REVISION



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INTRODUCTION

To Whom It May Concern:

This document contains information regarding the regulatory status of Okeanos product BC01. 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 Polyethylene 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 BC01 are compliant with the following legislations: FDA 21 CFR 174.500, 177.1520, 175.300 and 175.320, 178.2010 and 178.3297.

TH01: The ingredients in BC01 are compliant with the following legislations: 21 CFR 177.1520 for plastic olefin polymers and for food contact application.

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

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 Limit (SML(T)):

- OML: 10 mg/dm² (Article 12);
- 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.

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 BC01 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 BC01 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.

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.

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: BC01 complies with REACH Legislation Number 1907/2006 and is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

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.

TH01: The ingredients in BC01 are compliant with REACH (SVHC) requirements and do not contain Substances of Very High Concern (SVHC) above 0.1% (w/w).

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 BC01 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 ingredients in BC01 are compliant with CONEG / Directive 94/62/EC, as the sum of Lead, Cadmium, Mercury, and Hexavalent Chromium does not exceed 100 ppm.

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 Limit (SML(T)):

- OML: 8 mg/dm² or 50 mg/kg of food or food simulant (GMC 56/92)
- 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.

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

EC01: The ingredients in BC01 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.

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 Limit (SML(T)):

- OML: 10 mg/dm² 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.

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

Note — ANVISA RDC 727/2022: This regulation pertains to the labeling of processed foods and is therefore not applicable to this product.



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 suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it.

EC01: BC01 does not contain materials from genetically modified organisms and is compliant with Regulations EU 1829/2003 and 1830/2003.

ANIMAL DERIVED COMPONENTS (BSE/TSE)

BR01: To the best of our knowledge, this product is not manufactured or formulated with ingredients of animal origin.

EC01: BC01 does not contain Animal Derived Components (BSE/TSE).

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: BC01 does not contain plant derived components.

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 allergen-stimulating 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: BC01 complies with US Allergens FALCPA 2004 regulation and Food Allergens Regulation (EU) Number 1169/2011.

TH01: The ingredients in BC01 are compliant with EU and US FDA food allergen labeling requirements and do not contain any known food allergens.

PERFLUOROALKYL SUBSTANCES (PFAS, PFOS, PFOA)

EC01: BC01 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

TH01: The ingredients in BC01 are compliant with PFAS restrictions, as the product is formulated without the use of PFAS (Per- and Polyfluoroalkyl Substances).



CALIFORNIA PROPOSITION 65

TH01: The ingredients in BC01 are compliant with California Proposition 65 requirements and do not contain chemicals known to the State of California to cause cancer or reproductive toxicity above safe harbor levels.

HALAL

EC01: BC01 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 ingredients in BC01 are compliant with Halal requirements.

LATEX RESTRICTIONS

TH01: The ingredients in BC01 are compliant with rubber latex restrictions and are free from natural rubber latex.

KOSHER

TH01: The ingredients in BC01 are compliant with Kosher suitability requirements, as the raw materials are of mineral and petrochemical origin, containing no animal-derived ingredients, making them suitable for Koshe status.

RADIOACTIVE MATERIALS

TH01: The ingredients in BC01 are compliant with radioactive material safety requirements and are not contaminated with radioactive materials.

OZONE DEPLETING CHEMICALS

TH01: The ingredients in BC01 are compliant with requirements regarding ozone-depleting substances, as no ozone-depleting chemicals (ODS) are used in the manufacturing process.

PHTALATES & BISPHENOL A (BPA)

TH01: The ingredients in BC01 are compliant with phthalates and Bisphenol A (BPA) restrictions, as these substances are not intentionally added and are not expected to be present in the product.

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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