



REGULATORY DATA SHEET

BC02

FLEXIBLE PACKAGING LLDPE & LDPE

05/26 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 BC02. 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.

Nicolas Cuétara
General Counsel
Okeanos Group, LLC
legal@madefromstone.com / +1 949 4003041

FOOD & DRUG ADMINISTRATION

BR02: BC02 is in compliance with FDA CFR 21 regulations. 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).

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 BC02 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 BC02 are compliant with the following legislations: FDA Title 21 Section 176.

MX05: The ingredients in BC02 are compliant with FDA 21 CFR 178.3297 (Colorants for Polymers), 21 CFR 178.2010 (Antioxidants and Stabilizers for Polymers), and 21 CFR 177.1520 (Olefin Polymers) for food contact applications. The ingredients in BC02 are compliant with the U.S. Food Allergen Labeling and Consumer Protection Act (FALCPA), as no allergens are intentionally added to the product's formulation.

TH01: The ingredients in BC02 are compliant with the following legislations: 21CFR 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.



carbonate). FDA 21 CFR 177.1520 for plastic olefin polymers and for food contact application.

US02: Ingredients in BC02 are compliant to 21 CFR Food and Drugs, Sections 178.2010 Stabilizer for Polymers, 178.3297 Colorants for Polymers, Olefin Polymers FCNs and may be used as articles or components of articles intended for use in contact with foods in Table 1 and Conditions of use A-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 article meets both the technical and regulatory requirements of the intended application and does not modify the organoleptic properties of the food.

US03: Compliant with 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). And regulations 21 CFR 177.1520, 21 CFR 184.1409, and 21 CFR 178.2010.

EU FOOD CONTACT REGULATIONS

EC01: The ingredients in BC02 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.

MX05: The ingredients in BC02 are compliant with European Directive 94/62/EC Article 11 and CONEG requirements regarding heavy metals in packaging, with EU Regulation No. 10/2011 and its amendments on plastic materials and articles intended for food contact, with EU Food Allergens Regulation No. 1169/2011 as no allergens are intentionally added, with EU Regulation No. 1935/2004 on materials and articles intended to come into contact with food, with EU REACH Regulation (EC) No. 1907/2006 as the product does not contain any Substances of Very High Concern (SVHCs), with RoHS Directive 2015/863/EU regarding heavy metal content restrictions, and with EU Regulations 1829/2003 and 1830/2003 as the product does not contain any substances derived from genetically modified organisms. Note: no response was provided by the supplier for EU Regulation No. 2023/2006 (Good Manufacturing Practices) — confirmation should be requested directly from the compounder.

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 11 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.

US03: Complies with regulation (EU) 10/2011 amended by Regulation (EU) 2020/1245 or newer, and with regulation 2015/863/EU "Restriction of hazardous substances".

EU EC NO 1935/2004, EC 2023/2006, AND DIRECTIVE 2012/19/EU

IN01: The ingredients in BC02 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. It complies with the Packaging and Packaging Waste Directive 94/62/EC of the European Parliament.



US03: Compliant with regulation 94/62/EC. Does not contain (Cereals containing gluten (e.g. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof; Crustaceans and products thereof; Eggs and products thereof; Fish and products thereof; Peanuts and products thereof; Soybeans and products thereof; Milk and products thereof (including lactose); Nuts e.g. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof; Celery and products thereof; Mustard and products thereof; Sesame seeds and products thereof; Sulphur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂).

REACH (EU REGULATION (EC) NO. 1907/2006) / SUBSTANCES OF VERY HIGH CONCERN (SVHC)

EC01: BC02 complies with REACH Legislation Number 1907/2006 and is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

US03: This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

IN01: BC02 complies with REACH Legislation Number 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 23.01.2024, are not consciously used and are not expected to exceed the limit values.

HEAVY METALS REGULATIONS

EC01: The ingredients in BC02 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.

MERCOSUR FOOD CONTACT REGULATIONS

EC01: The ingredients in BC02 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 BC02 are compliant with MERCOSUR GMC Resolution Number 56/92, Resolution Number 39/19, Resolution Number 02/12 and Resolution Number 15/10.

MX05: The ingredients in BC02 are compliant with MERCOSUR GMC Resolution No. 56/92, with Resolution No. 39/19 (Positive List of additives for food contact packaging), with Resolution No. 02/12 (Positive List of monomers, initiating agents, and polymers for food contact), and with Resolution No. 15/10 regarding colorants for food contact, as no colorants are intentionally used in the product's formulation.

BRAZIL ANVISA FOOD CONTACT STATUS

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

MX05: The ingredients in BC02 are compliant with ANVISA RDC Resolution 105/1999 on the Positive List for food contact materials, with ANVISA RDC Resolution No. 326/2019 on additives, metal limits, phthalate-free requirements, solvents, and primary aromatic amines, with ANVISA RDC Resolution No. 56/2012 on monomers and starting substances for food contact, with ANVISA RDC Resolution No. 91/2011, and with ANVISA Food Allergens Regulation 26/2015 as no allergens are intentionally added. Note: RDC Resolutions 52/2010 and 51/2010 have not been tested by the supplier — formal confirmation should be requested directly from the compounder. ANVISA RDC 727/2022 is not applicable as it pertains to the labeling of processed foods.



MATERIALS FROM GENETICALLY MODIFIED ORGANISMS

US03: There are no raw materials that have been derived from genetically modified organisms (GMO).

EC01: BC02 does not contain materials from genetically modified organisms and is compliant with Regulations EU 1829/2003 and 1830/2003.

MX05: The ingredients in BC02 are compliant with GMO-free requirements, as the product is free of genetically modified organisms.

ANIMAL DERIVED MATERIALS (BSE/TSE)

EC01: BC02 does not contain Animal Derived Components (BSE/TSE).

IN01: Does not contain Animal Derived materials.

MX05: The ingredients in BC02 are compliant with plant-derived and animal-derived component requirements (BSE/TSE), as the product does not contain any substances of plant or animal origin.

PLANT DERIVED COMPONENTS

EC01: BC02 does not contain plant derived components.

MX05: The ingredients in BC02 are compliant with plant-derived and animal-derived component requirements (BSE/TSE), as the product does not contain any substances of plant or animal origin.

ALLERGENS

BR02: The ingredients that compose BC02 are in compliance with FDA, EU, and ANVISA allergen regulations.

EC01: BC02 complies with US Allergens FALCPA 2004 regulation and Food Allergens Regulation (EU) Number 1169/2011.

IN01: Complies for RDC No. 727/2022 and (EU) No. 1169/2011.

US03: Does not contain fish, shellfish, milk, eggs, soy, wheat (gluten), peanuts, tree nuts, and sesame seeds.

PERFLUOROALKYL SUBSTANCES (PFAS, PFOS, PFOA)

EC01: BC02 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

US03: PFOA/PFOS absent and PFAS absent.

MX05: The ingredients in BC02 are compliant with PFAS requirements, as no perfluoroalkyl or polyfluoroalkyl substances are added to the formulation.



HALAL

EC01: BC02 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.

MX05: The ingredients in BC02 are compliant with Halal requirements, as the product does not contain any substances illicit under Halal guidelines with no risk of cross-contamination with Haram substances on the production line.

CALIFORNIA PROPOSITION 65

TH01: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

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.

US03: 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.

MX05: The ingredients in BC02 are compliant with California Proposition 65, as no substances listed under the State of California's Proposition 65 as of the December 29, 2023 update or later are present in the product.

TOYS

TH01: Comply with EN71 Part 3 concerning the use in toy application.

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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