

REGULATORY DATA SHEET

BC02

FLEXIBLE PACKAGING LLDPE & LDPE

11/26 REVISION

Regulatory Data Sheet

BC02

FLEXIBLE PACKAGING LLDPE & LDPE

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 Sections 176 and 177.

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 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.

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.l70(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.

TH01: All additives and monomers used in BC02 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.

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.

MX05: The ingredients in BC02 are compliant with EU Regulation No. 1935/2004 on materials and articles intended to come into contact with food.

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 there of; 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 illinoiesis (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).

IN01: BC02 complies with REACH Legislation Number 1907/2006.

MX05: BC02 complies with EU REACH Regulation (EC) No. 1907/2006, as the product does not contain any Substances of Very High Concern (SVHCs).

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 23.01.2024, are not consciously used and are not expected to exceed the limit values.

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

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.

MX05: The ingredients in BC02 are compliant with European Directive 94/62/EC Article 11 and CONEG requirements regarding heavy metals in packaging, and with RoHS Directive 2015/863/EU regarding heavy metal content restrictions.

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 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.

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.

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

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

IN01: BC02 does not contain materials from genetically modified organisms and is compliant with Regulations (EC) 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.

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

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

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.

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: 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: BC02 complies with US Allergens FALCPA 2004 and does not contain fish, shellfish, milk, eggs, soy, wheat (gluten), peanuts, tree nuts or sesame seeds.

MX05: The ingredients in BC02 are compliant with EU Food Allergens Regulation No. 1169/2011, as no allergens are intentionally added to the product's formulation.

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.

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.

IN01: The formulation of BC02 does not contain, and is not manufactured with, any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

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

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

US03: PFOA/PFOS absent and PFAS absent.

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.

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

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.

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.

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.

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.

TOYS

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

LEGAL DISCLAIMER

Information contained in this publication or as otherwise supplied to users is believed to be accurate and is given in good faith; however, before using a product sold by Okeanos, or one of its a iliates, users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally. Okeanos and its a iliates MAKE NO WARRANTY; EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) OTHER THAN AS SEPARATELY AGREED BETWEEN THE PARTIES IN WRITING. All data exposed relate to average values representative of the production and should be considered only for information and not as contract values, Okeanos accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyrights and Designs cannot be assumed. MADE FROM STONE, OKEANOS, BIOTERRA, SEAFOAM and SHOAL and their respective designs are trademarks of Okeanos Group, LLC. All of Okeanos' products are made by utilizing and are associated with various forms of Okeanos' intellectual property, including patents and trademarks, which can be found at okeanos.global/patents and okeanos.global/trademarks

This product is not intended for the use in medical applications and should not be used in any such applications

Okeanos Group, LLC © 2026. Miami, FL 33130 - United States.