



REGULATORY DATA SHEET

BC09

MULTICAVIDY INJECTION MOULDING PE

05/26 REVISION

Regulatory Data Sheet

BC09

MULTICAVITY INJECTION MOULDING PE

INTRODUCTION

To Whom It May Concern:

This document contains information regarding the regulatory status of Okeanos product BC09. 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 resins 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 C 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.

IN01: BC09 is produced with PP Homopolymer & Calcium Carbonate or HDPE & Calcium Carbonate which is used as an indirect food additive in food packaging applications under 21 CFR (FDA).

These do not qualify as substances permitted for direct addition to human food or animal feed.

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.

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

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

IN01: The ingredients in BC09 are compliant with European Directive 94/62/EC Article 11.

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.

IN01: BC09 complies with REACH Legislation Number 1907/2006.

HEAVY METALS EU 94/62/EC AND COALITION OF NORTHEASTERN GOVERNORS

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.

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.

IN01: The ingredients in BC09 are compliant with MERCOSUR GMC Resolution Number 56/92, Resolution Number 39/19, Resolution Number 02/12 and Resolution Number 15/10.

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.

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

MATERIALS FROM GMOS (REGULATIONS (EC) 1829/2003 AND 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.

ANIMAL DERIVED COMPONENTS (BSE/TSE)

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

IN01: Does not contain Animal Derived materials.

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: BC09 does not contain plant derived components.

TH01: BC09 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.

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

CALIFORNIA PROPOSITION 65

BR01: This product does not contain any 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.

IN01: Does not use or intentionally add 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.



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: BC09.

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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