kēanos™

REGULATORY DATA SHEET

BC08

MULTIPURPOSE COMPOUND

05/26 REVISION

Regulatory Data Sheet

BC08

MULTIPURPOSE COMPOUND

REGULATORY STATEMENT

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 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 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 BC08 are FDA (Food and Drug Administration) compliant for use in food contact applications, according to FDA 21 CFR 177.1520.

IN01: BC08 complies with the general requirements for food additives listed at FDA Title 21 Section 176 . The section provides criteria for determining the safety of food additives, including substances generally recognized as safe (GRAS), food contact substances, and color additives.

EU REGULATION FOR FOOD CONTACT APPLICATIONS

BR01: The composition of BC08 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: Octene-1 (CAS:111-66-0) = 15mg/kg of food or food simulant;
- SML(T): Zinc Oxide (CAS: 1314-13-2) = 5mg/kg of food or food simulant;
- SML: Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate (CAS:2082-79-3) = 6mg/kg of food or food simulant.

The processing of BC08 follows the Good Manufacturing Practices Regulation (EC) No 2023/2006, allowing BC08 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 above-mentioned Migration Limits.

IN01: BC08 complies with the following regulations: Regulation (EU) Number 1169/2011, which establishes requirements for food information provided to consumers; European Commission Regulation (EU) Number 10/2011, which sets specific requirements for plastic materials and articles intended to come into contact with food; and European Directive 94/62/EC Article 11, which focuses on packaging and packaging waste management. These regulations ensure the safety, quality, and environmental responsibility of BC08.

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

BR01: BC08 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.

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

BR01: BC08 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 e ective date of this regulatory datasheet, that would require reporting under the regulation.

IN01: BC08 is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

MERCOSUR FOOD CONTACT STATUS

BR01: BC08 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: Octene-1 (CAS:111-66-0) = 15 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: BC08 complies with the regulations established by MERCOSUR GMC, including Resolution No. 56/92, which sets the general provisions for plastic food packaging materials; Resolution No. 39/19, which establishes specific migration limits for plastic food packaging materials; Resolution No. 02/12, which defines the positive list of monomers, other starting substances, and polymers for plastic food contact materials; and Resolution No. 15/10, which regulates the maximum limits of use for recycled plastics intended to be in contact with foodstuffs.

BRAZIL ANVISA FOOD CONTACT STATUS

BR01: BC08 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: Octene-1 (CAS:111-66-0) = 15 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: BC08 complies with the regulation outlined in ANVISA RDC Resolution No. 326/2019, ensuring adherence to the standards set forth by the regulatory authorities.

MATERIALS FROM GENETICALLY MODIFIED ORGANISMS (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.

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: BC08 is not manufactured or formulated with ingredients of animal origin.

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.

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, ca eine, 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: BC08 complies with the Brazilian regulation RDC No. 727/2022, as well as the European Union Regulation (EU) No. 1169/2011, ensuring compliance with both Brazilian and European regulatory standards.

CALIFORNIA PROPOSITION 65

BR01: BC08 complies with California Proposition 65, ensuring that it meets the necessary safety and environmental standards.

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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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