



REGULATORY DATA SHEET

BC12

FLEXIBLE PACKAGING

05/26 REVISION

Regulatory Data Sheet

BC12

FLEXIBLE PACKAGING

INTRODUCTION

To Whom It May Concern:

This document contains information regarding the regulatory status of Okeanos product BC12. 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

MX05: The components of BC12, comply with the following applicable sections of 21 CFR: 21CFR178.3297, 21CFR178.2010 and 21CFR177.1520.

EU REGULATION FOR FOOD CONTACT APPLICATIONS

MX05: The components of BC12 comply with European Commission Regulation (EU) Number 10/2011, and its amendments ; Regulation (EU) Number 1935/2004 and Regulation (EU) Number 2023/2006.

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

MX05: BC12 is not manufactured or formulated with any of the Substances of Very High Concern (SVHC).

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

MX05: The components of BC12, comply with European Directive 94/62/EC Article 11 and Coalition of north eastern governors (CONEG) as well as Heavy Metal Content RoHS Directive (2015/863/EU).

LATIN AMERICA MERCOSUR FOOD CONTACT STATUS

MX05: The components of BC12 comply with GMC Resolution Number 56/92; GMC Positive list of additives for packaging in contact with food Resolution Number 39/19; Positive List of Monomers starting agents and Polymers Resolution Number 02/12 and GMC Number 15/10.



BRAZIL ANVISA FOOD CONTACT STATUS

MX05: The components of the above mentioned BC12 comply with ANVISA RDC Number 105/1999, ANVISA RDC Number 326/2019, ANVISA RDC Number 56/2012, ANVISA RDC Number 91/2011, and ANVISA RDC Number 26/2015.

ANIMAL DERIVED COMPONENTS (BSE/TSE)

MX05: BC12 does not contain animal derived components.

PLANT DERIVED COMPONENTS

MX05: BC12 does not contain plant derived components.

FOOD ALLERGENS (RDC ANVISA 26/2015, REGULATION (EU) 1169/2011, FALCPA 2004 (US))

MX05: The components of the above mentioned BC12 comply with Food Allergens Regulation (EU) Number 1169/2011; Food Allergens Regulation Brazil ANVISA 26/2015 and FALCPA 2004 (US).

PERFLUOROALKYL SUBSTANCES (PFAS, PFOS, PFOA)

MX05: BC12 does not contain any PFAS (Perfluoroalkyl and Polyfluoroalkyl) substances.

MATERIALS FROM GENETICALLY MODIFIED ORGANISMS (REGULATIONS (EC) 1829/2003 & 1830/2003)

MX05: The components of the above mentioned BC12 does not contain materials from genetically modified organisms.

CALIFORNIA PROPOSITION 65

MX05: BC12 does not contain any other of the listed substances in the California Proposition 65.

HALAL

MX05: BC12 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.

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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