



REGULATORY DATA SHEET

Bioterra™ - M

BIODEGRADANT ADDITIVE

09/25 REVISION



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REGULATORY STATEMENT

To Whom It May Concern:

This document contains information regarding the regulatory status of Okeanos product Bioterra™-M. 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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EU DIRECTIVE 2015/863/EU (RoHS)

Bioterra™-M contains no intentionally introduced amounts of lead, cadmium, mercury, chromium, PBBs or PBDEs or phthalates.

EU REACH – ABSENCE OF SVHC

Bioterra™-M contains no intentionally added substances on the European Chemical Agency's Candidate List of Substances of Very High Concern at levels above the applicable threshold (0.1%).

CA PROPOSITION 65

Bioterra™-M contains no reproductive toxins or carcinogenic substances, per the state listing of chemicals, that would require a warning under the California Safe Drinking Water and Toxic Enforcement Act of 1986.

EU FOOD CONTACT STATUS: REGULATION NO 10/2011

Bioterra™-M complies with EU food contact Regulation No 10/2011.

FDA INDIRECT FOOD APPLICATIONS: FDA REGULATION 21 CFR 177.1520

Bioterra™-M is permitted for indirect food applications pursuant to FDA regulation 21CFR.



ANIMAL DERIVED MATERIALS

Bioterra™-M does not contain Animal Derived materials and it is NOT kosher certified.

PERFLUOROALKYL SUBSTANCES (PFAS, PFOS, PFOA)

PFAS are not used or added intentionally in the production of Bioterra™-M, and it does not intentionally contain phthalates.

ALLERGENS

Bioterra™-M does not contain any allergens.

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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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