



REGULATORY DATA SHEET

# Seafoam™

FOAMING ADDITIVE

09/25 REVISION



## Regulatory Data Sheet

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FOAMING ADDITIVE

## REGULATORY STATEMENT

To Whom It May Concern:

This document contains information regarding the regulatory status of Okeanos product Seafoam™. 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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## ORIGIN

**United States.**

## USDA FDA FOOD ADDITIVE REGULATIONS

Seafoam™ is identified as “general recognized as safe” (GRAS). FDA regulations permit chemicals that have GRAS status to be used in any packaging application where contact with food may occur, provided good manufacturing practices are followed. The base polymer used in the manufacturing of this product complies with section 21 CFR 177.1520. Please be advised that these products meet the FDA criteria in 21 CFR 177.1520 for food contact applications listed under conditions of use B through H in 21 CFR 176.170(c), Table 2 (temperatures not to exceed 212 F) as long as Good Manufacturing Practices are followed.

## EUROPEAN PLASTICS REGULATION (EU) NO 10/2011

The active ingredients in Seafoam™ are compliant with EU Regulation 10/2011 regarding plastic materials and articles intended to come into contact with food, and does not contain monomers, additives or other components which have SMLs or QMAs as specified by the regulation.

## EUROPEAN PLASTICS REGULATION (EU) NO 1935/2004

The components of Seafoam™ comply with article 17 of EC regulation 1935/2004. This compliance with article 3 of Regulation 1935/2004 needs to be tested on the final article. The components fulfill the requirements for food contact according to 1935/2004 based on the listing of all ingredients in EC regulation 10/2011.



To fully comply with food regulations in Europe, plastic materials and articles need to comply with, amongst other things, Overall Migration Limit requirements and Specific Migration Limits as specified in Commission Regulation (EU) No 10/2011 - when tested on the food contact surface with the appropriate food simulants and time/temperature test conditions. This is the responsibility of the manufacturer of the final article.

## **GMP REGULATION (EC) NO 2023/2006**

The components of Seafoam™ are produced in accordance with good manufacturing practice (GMP) as outlined in GMP Regulation (EC) No 2023/2006.

## **EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC**

The components of Seafoam™ comply with the heavy metals content requirements of the European Parliament and Council Directive 94/62/EC on Packaging and Packaging Waste (Directive 94/62/EC").

## **COMMISSION REGULATION 1895/2005/EC**

The components of Seafoam™ do not contain any intentionally added epoxy derivatives including BADGE, BFDGE, and/or NOGE as referenced in Commission Regulation 1895/2005/EC.

## **GERMAN FOOD, ARTICLES OF DAILY USE AND FEED CODE OF SEPTEMBER 1, 2005 (LFGB)**

The components of Seafoam™ are in compliance with German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 31, Plastic, Metal, Rubber Materials - LFGB Section 30 & 31 with Amendments, and BfR Recommendations in addition with relevant EU requirements, etc.

## **EUROPEAN PARLIAMENTARY REGULATION (EC) NO. 1907/2006**

The components of Seafoam™ do not contain any of the substances of very high concern (SVHC) outlined by the EU's REACH Directive as of the most recent edition dated 21 January, 2025, and does not contain any of the following chemicals that are outlined in RoHS (Directive 2011/65/EU): 1) Lead 2) Mercury 3) Cadmium 4) Hexavalent chromium 5) Polybrominated biphenyls 6) Polybrominated diphenyl ethers (PBDE) 7) Bis(2-ethylhexyl) phthalate (DEHP) 8) Butyl benzyl phthalate (BBP) 9) Dibutyl phthalate (DBP) 10) Diisobutyl phthalate (DIBP)

## **CHEMICAL COMPOUNDS**

The components of Seafoam™ do not contain Bisphenol A, Bisphenol S, Bisphenol F, and other ortho-Phthalates or their derivatives. The active ingredients in Seafoam™ are in compliance with the EU 10/2011. Below is the breakdown of the components of Seafoam™ with respect to their dual additives and/ or specific migration limits: Monosodium Citrate CAS#18996-35-5; no SML, it is a dual-use substance with E# 331 Calcium carbonate CAS#471-34-1; no SML, it is a dual-use substance with E# 170.

## **CALIFORNIA PROP 65**

Seafoam™ does not contain any of the chemicals or byproducts of decomposition listed under California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65) as updated January 3rd, 2025.



## ANIMAL DERIVED COMPONENTS (BSE/TSE)

Seafoam™ does not contain any raw materials produced from, or substances derived from animal origin. Moreover, these products are not derived from specific-risk materials as defined in European Commission Decision 97/534/EC. The manufacturing process does not use any ingredients of animal origin nor do our products come in contact with animal products during storage and transportation.

## BRAZIL ANVISA FOOD CONTACT STATUS

Seafoam™ complies with the Brazilian health regulations established by ANVISA (Agência Nacional de Vigilância Sanitária) for materials intended for food contact applications, based on the composition of its raw materials and supplier declarations.

Specifically:

- RDC Resolution No. 56/2012 – which regulates materials, packaging, and equipment intended to come into contact with food.
- RDC Resolution No. 326/2019 – which updates and complements RDC 56/2012, listing authorized additives and their conditions of use in plastic materials and coatings for food contact.

The ingredients are listed or are otherwise compliant under these ANVISA regulations, ensuring their safety and suitability for use in food packaging or handling applications within Brazil.

## FOOD ALLERGENS

Seafoam™ does not contain, nor are they manufactured with, any ozone depleting chemicals. We also certify that, as supplied, Seafoam™ does not contain or are manufactured in the presence of any allergens which include peanuts, tree nuts, milk, eggs, soybean, shellfish, fish, wheat, or sesame seeds.

## PERFLUOROALKYL SUBSTANCES (PFAS, PFOS, PFOA)

Seafoam™ does not contain intentionally added per- and polyfluoroalkyl substances (PFAS), including those identified under applicable regulatory definitions and frameworks such as:

- The U.S. Environmental Protection Agency (EPA) PFAS Master List of Chemicals
- EU REACH restrictions on PFAS (including the Annex XV proposal for a universal restriction)
- U.S. state-level PFAS regulations, including those enacted in California, Maine, Minnesota, and others
- The U.S. Toxic Substances Control Act (TSCA) Section 8 reporting and recordkeeping rule for PFAS (Final Rule published in 2023)

Furthermore, based on information provided by our raw material suppliers and our formulation process, there is no known presence of PFAS substances at or above 100 parts per billion (ppb), which is commonly referenced as a reporting threshold for many PFAS disclosure requirements.

## 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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