



REGULATORY DATA SHEET

Shoal™

NUCLEATING ADDITIVE

05/26 REVISION



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REGULATORY STATEMENT

This document contains information regarding the regulatory status of Okeanos product Shoal™ (US). Okeanos has relied upon the representations of third parties including vendors, suppliers, and manufacturing partners in the preparation of this document. 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.

FOOD & DRUG ADMINISTRATION

Under conditions of good manufacturing process and the limitations set forth below, Shoal™ is deemed to be suitable for use as a component of articles in contact with food in accordance with 21 CFR §174.5(d)(1), §174.5(d)(2), and §174.5(d)(4). The product is deemed to be in compliance with the purity requirements set forth in 21 CFR §174.5(a)(2) in that it is manufactured to comply with pre-established specifications.

Limitations: For use at levels not to exceed 2 percent by weight in polypropylene food contact articles in contact with all types of food under retort, i.e. FDA's Condition of Use A, and less severe conditions. Food types and conditions of use are as defined in 21 CFR §176.170(c), Tables 1 and 2.

EU REGULATIONS FOR FOOD CONTACT APPLICATIONS

The components of Shoal™ are listed in Annex I of the European Plastics Regulation (EU) No 10/2011. The components of Shoal™ are authorized for use under the European Plastics Regulation (as amended) as additives or polymer production aids, but are not authorized to be used as monomers or other starting substances or macromolecules obtained from microbial fermentation.

Shoal™ is deemed to be of a technical quality and purity suitable for the intended and foreseeable use in that it is manufactured to comply with pre-established specifications. No restrictions listed in Annex I or II of the European Plastics Regulation (such as SML, SML (T), QM) apply to the components of Shoal™. No compositional or purity specifications (as set forth in column 10 of the Union List) apply to the components of Shoal™.

Shoal™ contains the following dual-use additive: Calcium carbonate, E 170. There are no specifications of use for any components of Shoal™ in relation to the final article (as indicated in column 10 of the Union List). There are no other



specifications of use of which we are aware that need to be respected, or that the downstream user needs to establish, including those relating to types of food, time and temperature treatment and storage of food, or any other limitations. It is the responsibility of the manufacturer of the finished food-contact article to ensure that the Overall Migration Limit (OML) of 10 milligrams per square decimeter of surface area (10 mg/dm²) is met. Traceability of Shoal™ according to Regulation (EC) No 1935/2004 is ensured via the lot/batch number.

LATIN AMERICA MERCOSUR FOOD CONTACT STATUS

SHOAL™ complies with the general requirements set forth in Annex I of MERCOSUR/GMC/RES No. 03/92; CRITERIOS GENERALES DE ENVASES Y EQUIPAMIENTOS ALIMENTARIOS EN CONTACTO CON ALIMENTOS.

The monomer(s) and other authorized polymers and starting materials intentionally used to produce the polypropylene carrier resin constituent of SHOAL™ are listed in the Annex and/or are authorized in accordance with the requirements of MERCOSUR/GMC/RES. No. 02/12; REGLAMENTO TÉCNICO MERCOSUR SOBRE LISTA POSITIVA DE MONÓMEROS, OTRAS SUSTANCIAS DE PARTIDA Y POLÍMEROS AUTORIZADOS PARA LA ELABORACIÓN DE ENVASES Y EQUIPAMIENTOS PLÁSTICOS EN CONTACTO CON ALIMENTOS.

The additive constituents of SHOAL™ are listed in Table 1 of MERCOSUR/GMC/RES. No. 39/19; REGLAMENTO TÉCNICO MERCOSUR SOBRE LISTA POSITIVA DE ADITIVOS PARA LA ELABORACIÓN DE MATERIALES PLÁSTICOS Y REVESTIMIENTOS POLIMÉRICOS DESTINADOS A ENTRAR EN CONTACTO CON ALIMENTOS (DEROGACIÓN DE LA RESOLUCIÓN GMC No. 32/07). The following restrictions listed in Table 1 of MERCOSUR/GMC/RES. No. 39/19 apply to the constituents of SHOAL™:

N,N-Bis(2-hydroxyethyl)alkyl (C8-C18) amine; MCA no. 19; Reference no.: 39090; SML(T) = 1.2 mg/kg food (expressed as tertiary amine), where the SML(T) refers to the sum of the substances of MCA nos. 19 and 20; typical concentration in MPM 2000 < 100 ppm

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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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