

Stock Shapes
Base Polymer: PE500

Production No:
Reference No: SH01381FD0100_V01_2

Declaration on Food Contact

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Beynost, le 13/04/2022

Customer no.	Material	TECAFINE PE500 blue
Customer order no.	DIN-Designation	PE
Customer order date:	Production no.	
Order date	Description	Stock Shapes
Order no.		

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Dear Ladies and Gentlemen:

The polymer material used for the production of the above-mentioned semi-finished product is Polyethylene (PE).

Food contact according to the U.S. Food and Drug Administration (FDA):

According to the manufacturer's data, the PE base polymer meets the requirements for repeated contact with food according to FDA § 21 CFR 177. 1520 (Olefin polymers).

The used additives meets the requirements for repeated contact with food according to FDA 21 CFR § 178.3297 "Colorants for polymers" and 21 CFR § 178.2010 "Antioxidants and / or stabilizers". There are requirements regarding extractive limitations and conditions of use as specified in FDA § 21 CFR 177.1520. Adherence to these requirements has not been tested on the semi-finished product since they are usually referring to the final article. The exact provisions can be found at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>.

Declaration of Conformity in accordance with Regulation (EU) No 10/2011:

The aforesaid semi-finished product TECAFINE PE500 blue meets the applicable requirements of the Framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and of the Council Regulation (EC) No 2023/2006 on good manufacturing practice (GMP).

The raw materials used meet the applicable requirements set for the monomers and the other substances (additives, polymer production aids, colorants etc.) according to Regulation (EU) No 10/2011. As to the manufacturer's statement, the raw materials maybe contain monomers and additives or polymer production aids that are subject to a restriction by a specific migration limit (SML). In addition, no substances are contained which are also permissible as food

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additives. Partially, this information is provided only under a non-disclosure agreement for the purpose of conformance testing.

The manufacturer/distributor of the final product must verify compliance with the limits set under foreseeable or intended conditions of use. The final product must be subjected to a test for impairment of the smell and taste of test foods as well. Since the shape and surface of the stock shapes will be modified by customers in different ways, this examination was waived for the semi-finished product.

List of monomers and additives (additives, polymer production aids (PPA), food additives):

Monomer / Substance (additive, FCM PPA, food additive)	FCM	CAS	SML	Comments
other substances				available under NDA

Information on validity:

The present statement on food contact has been issued specifically for one particular order and cannot be transferred to other delivery or production numbers.

The materials mentioned herein are not suitable for medical and dental applications. Requirements in this area are to be requested separately.

The above information and statements are based on our current knowledge and are intended to provide information about our products and their uses. Thus, they do not assure or guarantee the chemical stability or the consistency of the products and their suitability for the trade in a legally binding way.

This statement refers to semi-finished products supplied by Ensinger France in Beynost and does not relieve the user of performing additional material testing which may be required to obtain product-specific approvals for the final product.

The suitability of the semi-finished products for a particular purpose must be ascertained by the component manufacturer or supplier under practical conditions of use.

Ensinger France

P.O.
Martine Marquezy
Responsable technique et qualité

This document has been generated electronically and is therefore valid without signature.

Documentation:

The documents from our raw material suppliers can be made available on request to the competent authorities or inspection bodies for the purpose of conformance testing.

This document may only be used by Ensinger colleagues who have successfully taken part in the training "handling non-ensinger-documents"! For some information regarding the training, please contact the Compliance-department in Nufringen: compliance@de.ensinger-online.com