

Declaration on Raw Material Compliance: FDA

Dear Ladies and Gentlemen:

The following declaration of conformity is intended to provide you as the user with information on requirements placed on our products for use in food contact according to the applicable provisions of the U.S. Food and Drug Administration (FDA). The data listed below is based on information from our raw material suppliers as well as our own research.

Information on validity:

The information listed in the present document apply to TECAFORM AH natural semi-finished products which are marked in the online catalogue as available on stock, with the exception of those labelled in the product number with „NF“ (non-food) or in the shipping documents as „not suitable for food contact“. The present statement applies to deliveries after 01.04.2014 and refers to semi-finished products supplied by Ensinger GmbH in Nufringen. Changes within the validity period will not be notified automatically. The current valid version can be found at www.ensinger-online.com. All previous versions lose their validity at the time of the publication of the subsequent version.

Information on the raw materials and the manufacturing process:

For the production of the above-mentioned semi-finished product made of thermoplastic polymer defined stock shape recipes are used. The raw material used is polyoxymethylene copolymer (POM-C) and optionally a small portion of processing agent.

In the manufacturing and processing of the raw material the manufacturer's recommendations are taken into account. Following extrusion, where appropriate, the semi-finished product is subjected to an annealing process in order to reduce tension. If appropriate, there is a tailoring in our cutting service. At Ensinger processing in form of planing or cutting is performed dry, without the use of coolant. The following statement includes planed or cut products. During grinding coolant is used, which may be present in trace amounts on the surface of the semi-finished product.

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

According to the manufacturer's data, the POM-C base polymer meets the requirements for repeated contact with food according to FDA § 21 CFR 177.2470 (polyoxymethylene copolymer). Any additives, that may be present, comply with appropriate, specific FDA Regulations. The resin is not suitable for types of food containing more than 15% alcohol [1]. There are requirements regarding extractive limitations and conditions of use as specified in FDA § 21 CFR 177.2470. 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 of § 21 CFR 177.2470 can be found at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>.

Please note:

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 GmbH in Nufringen 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

Stock Shapes
Base Polymer: POM-C

Document: HZ00200FD0200_V05_e
replaces Document: HZ_00200_FDA_1_V04_e
Validity: 01.11.2014 to 31.10.2016

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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 GmbH
i.V. 

Iris Schuller
Product Compliance Management

Documentation:

[1] Manufacturers of the polymers: Information on Food Contact, 2011/2012

The documents listed in this reference can be made available on request to the competent authorities or inspection bodies for the purpose of conformance testing.