

GUR[®] 4120

Food Contact Declaration

Please note that the manufacturer or seller of parts and articles made out of the above mentioned products have to take the full responsibility regarding applicable legal requirements.

The suitability of the finished article for the intended application (e. g. with respect to global migration limits) has to be checked by the manufacturer or seller.

Ticona is an ISO 9001 certified company. When manufacturing above listed products Ticona complies with the guidelines laid down in the Legislation EU 2023/2006.

EU: Regulation (EC) 10/2011

The monomers and additives used for the manufacturing of the above mentioned product are listed in the regulation (EC) 10/2011 from January 14th, 2011.

The above mentioned polymer compounds do not contain monomers or additives with a Specific Migration Limit (SML).

To fully comply with food regulations in Europe, the finished plastic article needs to comply with, amongst other things, Overall Migration Limit requirements and Specific Migration Limits as specified in (EC) 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.

<u>USA: FDA</u>

The above-mentioned product is compliant with applicable FDA regulations for food contact subject to the limitations below. The above mentioned product complies with the Code of Federal Regulations Title 21, CFR Part 177.1520 "Olefin Polymers", Specifications 2.1 and 2.2. of the Food and Drug Administration (FDA) of April 1, 2010².

This product may contain proprietary additives, all of which comply with the appropriate FDA regulations.

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¹ incl. amendment (EC) 1282/2011





Limitations:

Types of food	All types of food listed in 21, CFR176.170
Conditions of Use	All conditions of use listed in 21, CFR176.170
Application	Single or repeated use articles

Ticona GmbH, Product Safety.

Important: This assurance is accurate as of the date of issue based on the most recent version of any applicable regulations or standards unless otherwise stated above.

We are providing this information at your request, and, as such, nothing in this letter should be deemed to be or construed as an amendment or modification of any terms and conditions of sale under any contract in place between Ticona and you or any representation, guarantee, or warranty regarding such product and its characteristics, uses, suitability, safety, efficacy, hazards or health effects. Any liability or responsibility for such product shall be governed solely by, and any and all representations, guarantees, warranties regarding such product shall be solely as set forth in, the invoice or other contract for such shipments.

This information relates only to the above mentioned materials as delivered in their original packaging. It does not relate to any product made of these materials with or without the inclusion of further additives, such as processing aids or colorants. To the extent that any hazards may have been mentioned in this publication, we neither suggest nor guarantee that such hazards are the only ones that exist. This information should not be construed as a promise or guarantee of specific properties of the products described or their suitability for a particular application. Any existing intellectual property rights must be observed.

The responsibility for evaluating the finished food contact article for conformance with applicable requirements lies with the manufacturer of such article.

The products mentioned herein are not intended for use in medical or dental implants.





To: Sorensen&Kofoed A/S Ref: Your email dated on 15 November 2012 Date: 21 November 2012

FDA COMPLIANCE OF RUBBER HOSE

Polimer Kauçuk San.Paz.A.S declare that Rubber Hose ,code shown below , observe the "Drug and Food Administration" regulations and have been produced by using approved raw materials according to 21 CRF 177.2600 for rubber articles.

PRODUCT NAME ;

KEMI SD/16 UHMW-PE