

## Korea Engineering Plastics Co., Ltd.

Korea Engineering Plastics Co., Ltd. 84, Gorae-ro, Jangsaengpo, Nam-gu, Ulsan 680-050, Korea

Tel: 82-52-279-7830~4 /Fax: 82-52-279-7889 web: www.kepital.com or www.kepital.co.kr

To: Whom it may concern

Date: July 25, 2014

This is to certify that below mentioned-products comply with the following requirements.

KEPITAL F10-01

## **EU Legislation**

The Framework Regulation (EC) 1935/2004 sets out the general rules for all classes of food contact materials without giving any specific rule of how to prove the safety of food contact articles. Plastic materials are regulated by Regulation (EC) 10/2011 and its amendments.

The monomers and additives used for the manufacturing of the above mentioned products comply with commission regulation (EU) No 10/2011 and its amendment (EU) No 1282/2011, 1183/2012 and 202/2014. When manufacturing above listed product KEP comply with the "Good Manufacturing Practice" guidelines laid down in the Regulation (EC) 2023/2006.

The specific migration limits for the above products with KEPITAL base resin applies as follow;

FCM No.	Substance name	SML(mg/kg)
98	Formaldehyde	15
239	Melamine	2.5
255	1,3,5-Trioxane	5
363	1,3-Dioxolane	5
680	Triethyl-eneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methypl phenyl) propionate]	9

The above mentioned requirements of specific migration limits and overall migration limits have to be checked on the finished article by the manufacturer or seller.

## U.S. FDA

The above mentioned product is compliant with the applicable FDA regulations for food contact subject to the limitations below. The composition of product is compliant for use in food contact applications according to the CFR Title 21 177. 2470 "Polyoxymethylene copolymer". The antioxidants used in above mentioned product complies with the CFR Title 21 178.2010 "Antioxidants and/or stabilizers for polymers". Any additives, that may be present, comply with appropriate, specific FDA regulations.

Types of food	All types of food except foods containing 15% or more alcohol
Conditions of use	Use temperature shall not exceed 120 deg C per CFR 177. 2470
Application	Repeated use articles only per 21 CFR 177. 2470

Manufacturer of the finished article or seller has to evaluate the finished food contact article for conformance to FDA and other applicable requirements by themselves.

If you need further information, please feel free to contact us at the address shown above. Thank you.

Yours Sincerely,

Bong-Soo Kang, Quality Assurance Team Manager

Korea Engineering Plastics Co., Ltd.

Ulsan Plant

**DISCLAIMER**: The information contained herein is based on our current knowledge and investigations and is based on only above-mentioned product produced in Korea Engineering Plastics Co., Ltd ("KEP") as delivered in the original packaging. It doesn't relate to any products made of this product with the inclusion of more additives, such as processing aids or colorants. This information should not be construed as a promise or guarantee of specific properties of the product described or its suitability for a particular application. It is the sole responsibility of the users to investigate whether any existing patents are infringed by the use of this product. This product is not intended for use in medical and dental implants. Users should meet all safety and health standards. Any intellectual property rights are observed.