

POLYTRON

KUNSTSTOFFTECHNIK

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INFORMATION

on plastic materials and articles intended to come into contact with food

POLYTRON Kunststofftechnik GmbH & Co. KG herewith confirms for the use of semi-finished products and machined parts thereof, that

Fluorosint® 207 (PTFE MI)

with respect to its composition complies with the requirements of the US Food and Drug Administration (FDA) Title 21 Code of Federal Regulations (CFR) part 177.1550 (Fluoro polymers) under the given conditions of use.

Semi-finished products and machined parts thereof made from above mentioned plastic and intended to come into contact with food need to comply with the requirements of Regulation (EC) No. 1935/2004 in conjunction with Regulation (EU) No. 10/2011 in terms of Overall Migration Limit (OML) and Specific Migration Limit (SML) of the intentionally used monomers and other starting substances.

The compliance with the migration limits given in Regulation (EU) No. 10/2011 for materials and articles intended to come into contact with food depending on food category, contact time, contact temperature and ratio of food contact surface area to volume (S/V) must be checked by the user under the real/predictable application conditions and must be maintained during running operations! Even so the traceability of the used plastic materials and articles intended to come into contact with food must be proved! Upon request Polytron is able to support the user with documentation of own and/or supplier based migration tests.

It remains the responsibility of the user putting the articles into the intended use, to assess the final suitability for the intended food contact application under real application conditions! Please note the above given restrictions of use! We urgently recommend checking the compliance with the requirements of Regulation (EC) No. 1935/2004 in conjunction with Regulation (EU) No. 10/2011 based on the real conditions of use!

This statement has been automatically processed and is therefore not signed.

Note:

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