



STATEMENT OF SUITABILITY
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

Polytron PTFE 1000 (PTFE) natural/virginal

complies with the requirements of Regulation (EC) No. 1935/2004 in conjunction with Regulation (EU) No. 10/2011 on materials and articles intended to come into contact with food!

Furthermore POLYTRON Kunststofftechnik GmbH & Co. KG confirms that the semi-finished products and the machined parts thereof are manufactured according to Good Manufacturing Practices (GMP) as set out in Regulation (EC) No. 2023/2006 in an ISO EN 9001:2008 controlled process.

Following listed monomers and other starting substances included in the Union list of authorized substances set out in Annex I and II of Regulation (EU) 10/2011 are intentionally used for the manufacturing of semi-finished products and machined parts thereof.

FCM-No.	CAS-No.	Description	Restrictions
281	0000116-14-3	Tetrafluorethylene	SML = 0,05 mg/kg

as well as other proprietary substances which will be disclosed to third parties (e.g. test laboratories) under the terms of a non-disclosure-agreement only!

SML = specific migration limit, SML(T) = total specific migration limit, OML = overall migration limit

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.

In addition to the statement given above Polytron Kunststofftechnik GmbH & Co. KG declares that the material used at present complies with respect to its composition 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.

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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