



DECLARATION OF COMPLIANCE
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

UltraWear® GS (PE-UHMW MO)

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
125	0000074-85-1	Ethylene	SML = 60 mg/kg
		Zinc stearat	SML = 25 mg/kg, expressed as zinc

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

The conformity with the requirements of Regulation (EC) No. 1935/2004 in conjunction with Regulation (EU) No. 10/2011 was tested for all foods with simulants A, B and D2.

The specific migration limit (SML) was tested at contact temperatures up to 40°C and with a contact time of 30 days maximum.

The overall migration limit of 10 mg/dm² (OM) was determined under standardized testing conditions OM2 and OM5.

The tests were run with a ratio of food contact surface area to volume (S/V) of 6 dm²/kg.

If the migration limit is exceeded for specific foodstuff, the specification can be adhered by reducing the contact surface of the article relative to the volume of food by changing the design and/or by reducing contact time and/or contact temperature.

At present time the material used does not comply with the requirements of the US Food and Drug Administration (FDA).

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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