

EU Declaration of Compliance (DoC) for Food Contact Materials

Polyurethane tubing range L:K:S
OD 4mm, 6mm, 8mm, 10mm, 12mm, 14mm, 16mm
Colors: transparent, dark blue translucent, black translucent light

Manufacturer:
PAPUREX W. Büchner GmbH, Klein-Breitenbach 4a, D 69509 Mörlenbach

We hereby declare, that above mentioned product range **L:K:S** complies to the provisions of directives (EU) No. 10/2011 as well as (EU) No. 1935/2004. Global migration, as well as the specific migrations tests, showed no results exceeding the legal limits.

The composition of the products complies with the requirements of the Commission Regulation (EU) No. 10/2011

The colored products contain additives which are in compliance with Commission Regulation (EU) No. 10/2011 amended up to the Regulation (EU) No. 2019/1338.

A specific migration limit (SML) is applicable for the following substances:

dark blue translucent	Aluminium	SML (T) = 1 mg/ kg
dark blue translucent	Barium	SML (T) = 1 mg/ kg
dark blue translucent / black translucent light	Kupfer/ Copper	SML (T) = 5 mg/ kg

This statement is based on the information provided by our suppliers.

This product does not contain dual-use-additives.

The substances used for the manufacturing of our above mentioned products are according to FDA Regulation

21 CFR § 177.2600 Rubber Articles Intended for Repeated Use
and 21 CFR § 178.3297 Colorants for polymers

Global migration was tested by Dekra Automobil GmbH, Stuttgart
Prüfbericht PB 2004801

Migration experiments with food simulants A and B were performed at 2h/ 70°C and include suitability for 15 minutes/ 100°C.

Migration experiments with food simulants C, D1, D2 and E were performed at 0,5h/ 40°C.

The limits for global migration according to article 12 (1) of the Commission Regulation (EU 10/ 2011 of 10 mg/ dm² were not exceeded by the tested food simulants on first migration result.

The stated test results confirm suitability for contact with all types of food stuff, according to the tested contact time and temperature.

Regarding working temperatures there are to be considered the regarding limits of pressure load according to our data sheet. Individual testing regarding applied pressure load on specific use through the customer is obligatory.

Our ISO 9001 certified quality management system monitors the GMP-compliant way of manufacturing so that product contaminations of the **L:K:S** can be excluded. Traceability of our production batches is guaranteed.

The **L:K:S** gets foiled directly after production process in our factory to ensure safety from pollution. The tubing gets delivered without any marking to enable its outside safe for food contact as well. We recommend cleaning of contact surfaces after installation and before putting into service. Given different contact conditions, the user is obligated to do own tests to ensure suitability of above mentioned products.

Mörlenbach, 02.11.2021

Luitgard Wrba, Quality manager

Validity: 23.09.2022