

Declaration of Conformity

This Declaration of Conformity includes all tubes of Novoplast product line „**Master-Tube PUR 98A Food**“ made of polyurethane 98 Shore A Ether, according to the currently relevant data sheet.

Information on the raw materials used

- The material manufacturer confirms that the raw materials and additives used for the production are listed in the Code of Federal Regulations, Title 21 § 177.2600 "Rubber articles intended for repeated use" and § 178.2010 "Antioxidants and/or stabilizers for polymers" of the FDA.
- The raw materials used comply with Regulation (EU) No 10/2011. However, it must be ensured that no detectable quantities of primary aromatic amines are present in the migrate product during the applicable migration test and that global migrations, specific migration and other material restrictions are within the scope of (EU) 10/2011. In addition, finished products must not impair the appearance, smell and taste of the food.
- The monomers used in the raw materials are listed in the Consumer Goods Ordinance in the version of the notification dated 23 December 1997 (BGBl, 1998 I p. 5), last amended on 24 June 2013. The monomer raw materials are listed in Chapter 2 of Recommendation XXXIX "Polyurethane based consumer goods" of the BfR of June 1, 1998, as amended on January 1, 2012.

Details of the Novoplast product line "Master-Tube PUR 98A Food"

Based on the results of laboratory tests carried out by an accredited institute, we declare that the printed, natural-coloured tube sections (internal diameter 2 - 11 mm; wall thickness ≤ 2.5 mm) made of polyurethane meet the requirements of Regulation (EU) No. 10/2011, including its latest amendments, with the following restrictions:

1. Under the applied testing conditions used (standardized testing condition OM 3, repeated-use) the aforementioned tube is suitable for contact with all foodstuffs which are according to Table 2, annex III of Regulation (EU) No. 10/2011 assigned to food simulants A and B, under any conditions that include heating up to 70 °C for up to 2 h, or up to 100 °C for up to 15 min.
2. The above-mentioned tube is also suitable for repeated-use contact with all kinds of foodstuffs which are according to Table 2, annex III of Regulation (EU) No. 10/2011 assigned to food simulants C and E provided that the contact time of 30 min at up to 40 °C is not exceeded.
3. With the exception of food intended for infants and young children the above-mentioned tube is also suitable for contact with all kinds of foodstuffs which are according to Table 2, annex III of Regulation (EU) No. 10/2011 assigned to food simulants D1 and D2 provided that a contact time of 30 min at up to 40 °C is not exceeded.
4. Due to the exceeding of the overall migration limit with simulants D1 and D2 given in mg/kg FS the aforementioned tube may not be used in contact with foodstuffs used for the production of food intended for infants and young children. This refers to all foodstuffs assigned to food simulants D1 and D2.
5. The above-mentioned test items may not be used as single-use articles, because they have not been tested for this application.
6. The conditions of use given under 1. to 5. have to be specified definitely on the labelling or in the directions of use to preclude an unintentional improper use.

A MASTERFLEX GROUP COMPANY

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Information on food contact

Date of issue: 15.10.2019

With regard to the restrictions given in 1. to 6., the aforementioned product in our opinion also meets the requirements of Regulation (EU) No. 1935/2004 and the German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch, LFGB).

The GMP conform production of the tubes according to Regulation (EC) No 2023/2016 (Good Manufacturing Practice) and an ISO 9001-certified quality management system prevent product contamination and ensure consistent product quality and traceability.

The aforementioned tube must be cleaned with alkaline or acidic cleaning agents before first use. In order to safely exclude possible rest risks of product contamination for the protection of the consumer, the medium must be completely rinsed off after cleaning. Furthermore, we recommend that in the case of printed tubes, contact between the printed text on one side and the foodstuff is avoided if possible, as the printing ink used does not have food approval. According to the regulation (EC) No. 1907/2006 (REACH) the printing ink used does not contain any substances of concern.

Added components, changes due to use or subsequent changes are expressly excluded. This declaration loses its validity in the case that the product is not used in accordance with the conditions specified in applicable regulations, at the latest, on 02.01.2024.

For further questions please contact

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