

08-02-2022

Declaration of Compliance

This Declaration of Compliance covers the following products:

Product number	Product name and material:	Sample no. / Test report
001025	Medicine cup, clear	
001026	Medicine cup, blue	
001027	Medicine cup, red	392-2018-00254505
001028	Medicine cup, yellow	
001029	Medicine cup, green	

We confirm that the abovementioned articles fulfill the requirements on materials and articles used for food contact as described in the European Regulation 10/2011/EC, including subsequent amendments up to Commission Regulation (EU) 2020/1245.

Monomers and additives used for the manufacturing of the abovementioned materials are all listed in Annex I of Regulation 10/2011/EC, including subsequent amendments up to Commission Regulation (EU) 2020/1245.

The articles contain no substances restricted by specific migration limits:

The articles contain the following substances which are subject to a restriction in food:

- Cas no. 1592-23-0: Calcium Stearate (E470)
- Cas no. 31566-31-1: Glycerol Monostearate (E471)
- Cas no. 14807-9601: Talc

Migration tests have been conducted according to the specifications set out in Regulation 10/2011/EC, including subsequent amendments up to Commission Regulation (EU) 2020/1245 in test report as specified in the table.

The products have been tested in food simulant A, B and D2 according to OM2. They can therefore be applied for any longterm storage at room temperature or below, including heating up to $70\,^{\circ}$ C for up to 2 hours or up to $100\,^{\circ}$ C for up to $15\,^{\circ}$ C minutes.

The materials do not represent a functional barrier as defined in EC-regulation 10/2011/EC and 2020/1245.

The products do not apply any danger to health or environment according to Framework Regulation 1935/2004/EC. The products are manufactured according to Regulation 2023/2006/EC on good manufacturing practice (GMP). The materials comply with current EU-legislation on plastic materials and articles intended for food contact as described in EC Regulation 10/2011/EC and 2020/1245 as amended.

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