

## Regulatory Information Sheet

# FOOD CONTACT COMPLIANCE EUROPE

Machines-3D hereby confirms that articles made from the products listed in Table 1 below, when produced in accordance with good manufacturing practice, comply with the requirements of the European Community regulations for plastics used in food-contact applications. These include the following Regulations :

- A) Regulation (EC) No 1935/2004 on Materials and Articles intended to come into contact with food
- B) Commission Regulation (EU) No 10/2011 on Plastic Materials and Articles intended to come into contact with food (PIM, Plastics Implementation Measure)
- C) Commission Regulation (EC) No 321/2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles
- D) Commission Regulation (EC) No 1282/2011 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- E) Commission Regulation (EC) No 1183/2012 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- F) Commission Regulation (EC) No 202/2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- G) Commission Regulation (EC) No 2015/174 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- H) Commission Regulation (EC) No 2016/1416 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

**Table 1.**

Product	Material
FUSION-X	PETG Bio-Copolyester

All the monomers used in the production of the products listed in Table 1 comply with the positive list of monomers and restrictions contained in EU No 10/2011 and subsequent amendments.

Products listed in Table 1 contain the following monomers, which are listed in ANNEX 1 of EU 10/2011 :

**Table 2.**

FCM substance No.	Substance name	SML(T) [mg/kg]	Restrictions and specifications
227	ethylene	3	None
785	terephthalic acid	7.5	None
210	1,4-bis(hydroxymethyle) cyclohexan	None	None

In addition to the three monomers listed above, the products listed in Table 1 also contain the following monomer listed in EC 2015/174

**Table 3.**

FCM substance No.	Substance name	SML(T) [mg/kg]	Restrictions and specifications
364	1,4:3,6-dianhydrosorbitol	5	<p><b>Only to be used as :</b></p> <ol style="list-style-type: none"> <li>(a) a co-monomer in poly (ethylene-co- isosorbide terephthalate)</li> <li>(b) a co-monomer at levels of up to 40 mole % of the diol component in combination with ethylene glycol and/or 1,4- bis(hydroxylmethyl)cyclohexane, for the production of polyesters.</li> </ol> <p><b>Polyesters made using dianhydrosorbitol together with 1,4-bis(hydroxyl methyl)cyclohexane shall not be used in contact with foods containing more than 15 % alcohol.</b></p>

Migration tests, conducted on Materials in Table 1 showed that the articles met the global migration limit of 60 mg/kg of food or 10 mg/dm<sup>2</sup> of the plastic and the specific migration limits for terephthalic acid (7.5 mg/kg of food) and glycols, ethylene and diethylene (30 mg/kg of food)

In respect to the qualitative composition and the values obtained for the overall migration, specific migration and residual content, the use of the above products for direct contact with aqueous, acidic, ethanolic (up to 15%) and fatty foodstuff for 30 minutes at 70°C, and subsequently for any time at room temperature, is considered to be safe for public health.

The Materials listed in Table 1 comply with the requirements of EU 10/2011 as amended by EU 174/2015 and may be used with all food types, with the exception of foods containing greater than 15% alcohol, at temperatures up to 100°C followed by long-term storage at ambient temperature or below.

Articles intended for contact with food manufactured from the above products will also meet the requirements of EC 1935/2004 provided they have been manufactured according to the requirements of Commission Regulation 2023/2006(Good Manufacturing Practice).

#### **Further information**

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