

STYRON™ 678E Clear Polystyrene

The composition of our polystyrene material STYRON™ 678E Clear Polystyrene as supplied from our factory, complies with the requirements for use in contact with food of the legislation, of the European Union and its Member States:

Fully harmonised legislation at Community level applicable for all European Union Member States

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| EU | <p>Commission Regulation (EU) No 10/2011 (14.1.2011) on plastic materials and articles intended to come into contact with food, ANNEX I, Table 1 (and its amendments: Commission Implementing Regulation (EU) No 321/2011 (1 April 2011) Commission REGULATION (EU) No 1282/2011 (28 November 2011) Commission REGULATION (EU) No 1183/2012 (30 November 2012) Commission REGULATION (EU) No 202/2014 (3 March 2014) Commission REGULATION (EU) No 174/2015 (5 February 2015) Commission REGULATION (EU) No 1416/2016 (24 August 2016) COMMISSION REGULATION (EU) 2017/752 of 28 April 2017 Commission Regulation (EU) 2018/79 of 18 January 2018 Commission regulation 2018/213 of 12 February 2018 Commission Regulation (EU) 2018/831 of 5 June 2018 Commission Regulation (EU) 2019/37 of 10 January 2019 Commission Regulation (EU) 2019/1338 of 8 August 2019 Latest amended by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (applies to all EU-Member States)</p> |
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With reference to Article 11, item 3 of Commission Regulation (EU) No 10/2011 (as amended):

- No substances, which are subject to a restriction in food based on Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives incl. subsequent amendments like COMMISSION REGULATION (EU) 2020/1819 of 2 December 2020 or Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods incl. subsequent amendments like COMMISSION REGULATION (EU) 2020/1681 of 12 November 2020, are present in this product.

In reference to Article 3 of Regulation (EC) No 1935/2004 concerning the generic product safety requirements of materials and articles intended to come into contact with foodstuffs:

- This resin is manufactured in accordance with good manufacturing practice as outlined in Commission Regulation (EC) No 2023/2006 of 22 December 2006.

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- The raw materials used for the manufacturing of this resin are of a suitable purity for articles intended for use in contact with foodstuffs.

However, good manufacturing practice needs to be applied during processing of the polymer, including adherence to the maximum recommended processing temperatures.

- All monomers and additives used in the manufacturing of this resin are listed in Commission Regulation (EU) No 10/2011.
- TRINSEO does not on a routine basis perform organoleptical tests on articles produced from this resin.

Please note that it is the responsibility of the manufacturers of the finished food contact article and/or the industrial food packers to ensure that the article in its final application does not bring about a deterioration of the organoleptical characteristics of the foodstuff.

- Parameters such as applied processing conditions and any modification of the resin during processing is beyond the control of TRINSEO.
- Thermal emissions may be generated during processing of the resin under typical processing conditions.
- Since these emissions could have an impact on the organoleptical properties of the final products, it remains the responsibility of the manufacturer of the finished food contact article and the industrial food packer to make sure that the requirements of Regulation (EC) No 1935/2004, Article 3, pertaining to the final articles, are met.

Based on the considerations above as well as on our own safety assessments of all raw materials used in the manufacturing of this resin and provided that good manufacturing practice is applied during processing of this resin, we can confirm that this resin as supplied is in compliance with Article 3 of Regulation (EC) No 1935/2004.

Further, systems and procedures are implemented in the manufacture of this resin in order to fulfill the requirements of Article 17 of Regulation (EC) No 1935/2004 re. traceability. Article 17 applies as of 27 October 2006.

We like to draw your attention to the fact that Commission Regulation (EU) No 10/2011, which applies to all EU-Member States, includes a limit of 10 mg/dm² on the overall migration from finished plastic articles into food.

In accordance with Commission Regulation (EU) No 10/2011 the migration should be measured on finished articles placed into contact with the foodstuff or appropriate food simulants in accordance with ANNEX III of Commission

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Regulation (EU) No 10/2011 for a period and at a temperature which are chosen by reference to the contact conditions in actual use, according to the provisions in Article 22 of Commission Regulation (EU) No 10/2011.

As an alternative, generally recognised diffusion models based on experimental data can be used for the estimation of the migration of a substance.

STYRONTM 678E Clear Polystyrene does contain a substance for which a specific migration limitations (**SML**) is imposed by the EU/EFTA-member countries.

SML1: 5 mg/kg, zinc from zinc salts (Annex II). Migration testing on zinc on representative samples has shown the level to be well below this limit.

The statement is based on risk assessment of migration into food covered by the following conditions of use: all food types temperature/duration: 60 °C/10 days, 70 °C/2 h.¹

Regulation (EU) No. 2020/1245

To verify the requirements of this regulation, tests and calculations have been carried out,¹ and raw materials have been reviewed.

Concerning metals listed in Annex II Table I, and for Primary Aromatic Amines (recital 24, Annex II point 2) representative grades have been tested and found to meet the requirements of the regulation.

To the best of our knowledge, based on our risk assessment and migration testing, non-listed substances for which genotoxicity cannot be ruled out, will not migrate into food at or above 0.15 ppb for the conditions of use referred to above.

Finished products regulatory requirement

End-use article manufacturers using the above product for the fabrication of finished products (materials/articles) intended to come into contact with food are responsible for and must comply with the relevant food contact restrictions/limitations (for example OML, SML and other analytical requirements). They are also required to comply with the general regulatory requirement (Regulation (EC) No. 1935/2004, Art. 3) that these materials/articles do not bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics (smell and taste) thereof.

¹ Representative [samples](#) have been tested.

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This statement has been written to the best of our knowledge and based on the available information at the time of preparing the document.

The appropriate regulations should be consulted for complete details.

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