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the fast extrusion company

Food Contact / FDA
ABS Standardtype Virgin

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Food Contact

The composition of ABS Standardtype Virgin as supplied from manufacturer's factory, complies with the requirements for use in contact with food of the legislation of the European Union and its Member States:

Fully harmonized legislation at Community level applicable for all European Union Member States.	
EU	Commission Regulation (EU) No 10/2011 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 April 2017 Commission REGULATION (EU) 2018/79 of 18 January 2018 Commission REGULATION 2018/213 of 12 February 2018 Commission REGULATION 2018/831 of 5 June 2018 Commission REGULATION 2019/37 of 10 January 2019 Latest amended by Commission Regulation (EU) 2019/1338 of 8 August 2019 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) (The EU Commission Directive 2002/72/EC and its amendments, EU-Directives 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC and EU Commission Regulation (EC) No 975/2009 are repealed as of 1 May 2011)

With reference to Article 11, item 3 of Commission Regulation (EU) No 10/2011, (as amended), no substances which are subject to a food contact restriction set forth in EU-Directive 95/2/EC (20.2.1995), as amended (including EU-Directive 2010/69/EU (22.10.2010)), are present in this product.

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

Good manufacturing practice also must be applied during processing of the polymer, including adherence to the maximum recommended processing temperatures.

- All monomers and additives used to manufacture this resin are listed in Commission (EU) No 10/2011.
- The manufacturer does not perform on a routine basis 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 articles 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 the manufacturer.
- Thermal emissions may be generated during processing of the resin under typical processing conditions.
- Since thermal emissions may impact 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 consideration above as well as on manufacturer's 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 fulfil the requirements of Article 17 of Regulation (EC) No 1935/2004 regarding traceability. Article 17 applies as of 27 October 2006.

Please note that Commission Regulation (EU) No 10/2011, 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 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 recognized diffusion models based on experimental data can be used for the estimation of the migration of a substance.

Also, specific migration limitation **(SML)** for certain substance of this resin is imposed by the EU/EFTA-member countries as follows:

- Acrylonitrile (PM/REF# 12100) specific migration has to be nondetectable (ND) with a detection limit 0.01 mg/kg food. (Remark: The analytical tolerance applicable for this detection limit (and analytical method) has not been defined. The manufacturer understands that regulatory guidance will be available in the future.)

- 1,3-butadiene (PM/REF# 13630) specific migration has to be not detectable (detection limit of method 0.01 mg/kg food) or alternatively, residual butadiene content in the finished article has to be less than 1 mg/kg.
- Also specific migration limits (SML) for certain ingredients of this resin are imposed by Regulation (EU) No 10/2011.

Depending on the processing conditions, the residual acrylonitrile monomer content in the finished article may vary; therefore the specific migration levels of acrylonitrile should to be carefully monitored.

The compliant use of ABS plastic may be limited to specific food contact conditions and/or food types. For example, higher acrylonitrile migration has been observed with certain food simulants (e.g., dairy products, “higher fat” and or “high alcohol” content foods). Also, elevated temperature storage conditions have been shown to impact the level of acrylonitrile migration.

It is the responsibility of both the manufacturers of finished food contact articles and the industrial food packers to make certain that these articles in their actual use are in compliance with the imposed specific and overall migration requirements. It is also the responsibility of the manufacturer of the finished food contact article and the industrial food packers to provide final users with adequate instructions on product use, including possible restrictions for their safe and compliant use.

FDA

Food Additive Regulation 21 CFR 181.32 provides for the use of acrylonitrile copolymers, such as this resin, as articles or components of articles intended for use in contact with food with certain prescribed conditions. An important condition is that tests be performed using the finished food-contact article in order to determine acrylonitrile monomer extraction. In the case of repeated-use articles, the limitation of acrylonitrile extraction for finished food-contact articles is 0,003 mg/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to intended conditions of use.

Extraction studies using laboratory test specimens exposed to food solvents have been conducted. The manufacturer has concluded that this resin will comply with 21 CFR 181.32(a)(3)(i) when used in rigid and semi-rigid food-contact articles intended for repeated use applications and at temperatures below 212 °F.

The uses cited above are subject to good manufacturing practices and any limitations, which are part of the regulations. The regulations should be consulted for complete details.

With best regards
Universal Polythex Kunststoffe GmbH