

Food Contact Statement – PS Virgin

Version 1.2

The manufacturer hereby declares that regarding the composition of the product the basic polymer chemically consists of polystyrene and complies with the relevant aspects of the following food contact regulations on materials and articles:

EU (European Union) Food Contact Regulatory Compliance Statement

Commission Regulation (EU) No. 10/2011 as amended^{1,2}, Annex I (Union list of authorised substances). If present, the monomers and additives being subject to restrictions or specifications are mentioned below.

Abbreviations used below:

OML = Overall Migration Limit of surface area of material or article [mg/dm²] or in food simulant [mg/kg];

SML = Specific Migration Limit in food or in food simulant [mg/kg].

SML(T) = Specific Migration Limit for a group of substances [mg/kg].

FCM No. = Unique identification number of the substance

ND = Non-detectable, a detection limit of 0,01 mg/kg food is applicable unless specified differently.

Finished products fabricated with the above product must comply with the following restrictions when placed on the market in any of the EU Member States or in non-EU countries which have adopted the same legislation³:

OML: 10 mg/dm² or 60 mg/kg food (Article 12).

and

SML 1: butadiene (CAS No. 106-99-0; FCM No. 223): ND; with a specific restriction for this substance of 1 mg/kg in final product.

SML 2: 5 mg/kg, zinc from zinc salts (Annex II).

SML 3: octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CAS No. 2082-79-3; FCM No. 433): 6 mg/kg; When applicable, the migration results for this substance can be corrected by the Fat Consumption Reduction Factor as explained in Chapter 4, Annex V of the Regulation (EU) No. 10/2011.

SML 4: 2,4-Bis(octylthiomethyl)-6-methylphenol (CAS No. 110553-27-0; FCM No. 756): 5 mg/kg (SML(T) expressed as the sum of the substances FCM Nos 756 and 758) ; When applicable, the migration results for this substance can be corrected by the Fat Consumption Reduction Factor as explained in Chapter 4, Annex V of the Regulation (EU) No. 10/2011.

¹ Commission Regulation (EU) No. 10/2011 replaced Directive 2002/72/EC and its amendments on May 1st, 2011.

² Commission Regulation (EU) No. 10/2011 of 14 January 2011, as lastly amended by Commission Regulation (EU) No. 1338/2019 of 8 August 2019.

³The SML restrictions listed above to be checked by the final article producer are those assessed as being above 1/10th of the SML restrictions listed in Regulation (EU) 10/2011 assuming standard conditions of use (= 10 days, 40°C, 1kg of food in contact with 6 dm² of cubic packaging, 250 µm thickness).

Dual use additives

The manufacturer has, to the best of manufacturers knowledge, reviewed the substances which are used as additives in the manufacture of the above mentioned product regarding dual use additives, meaning additives that are approved for food contact materials according to Regulation 10/2011/EC and as direct food additives according to Regulation 1333/2008/EC and 1334/2008/EC and found no substances which can be classified as dual use substances.

Regulation (EC) No. 1935/2004, Article 3

The manufacturer declares that the composition of the above product complies with the relevant requirements of Article 3 of the above Regulation, provided the end-use restrictions are met under normal conditions of use.

Regulation (EC) No. 1935/2004, Article 17

Concerning the traceability of the used raw materials, the manufacturer can state that there is a system in place which enables the control of the material stream in the production and to trace the materials back to their upstream suppliers.

Good Manufacturing Practice Regulation (EC) No. 2023/2006

With regards to compliance with the provisions given in Commission Regulation (EC) No. 2023/2006, there are systems in place which control and document as required for Food Contact Good Manufacturing Practice.

Migration testing for food contact applications

Concerning Specific Migration Limits, based on migration calculations for the restricted additives, the SMLs should not be exceeded on the use of the above mentioned material in food contact applications. This refers to standard conditions of use (= 10 days, 40°C, 1kg of food in contact with 6dm² of cubic packaging, 250 µm thickness). The manufacturer is not aware of any restriction on the use with specific types of food.

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.

US FDA Status

This product meets the specifications of the United States FDA Food Packaging Regulation 21 CFR 177.1640 (polystyrene and rubber modified polystyrene). By virtue of this compliance, this resin may be used as a component of articles for use in contact with food. There are no regulatory food type or temperature restrictions on this resin as defined under 21 CFR 176.170(c).

This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

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 all relevant food contact restrictions/limitations as set forth in the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations. Further, as stated in 21 CFR 174.5, it is the responsibility of the end-use article manufacturers to ensure that the article is appropriate for its intended food-contact use, and that its use does not cause adulteration of food.

European Standard EN71 - Safety of Toys

European Standard EN71-3:2013 + A1:2014 + A2:2017 + A3:2018 + A4:2019 sets limits on the migration of several metals. The manufacturer wishes to inform that based on the information on the raw materials used to produce the above grade the manufacturer does not deliberately add any of these metals or their concentrations would not exceed the migration limits set in the above mentioned standard.

Heavy metals

The sum of lead, cadmium, chromium-VI and mercury does not exceed the maximum value of 100 ppm (i.e. 0.01%) as required by the CONEG (Coalition of North Eastern Governors) for the January 1, 1994. Thus, also the maximum value for these elements laid down in Directive 94/62/EC as last amended by Commission Directive (EU) 2018/852 is met.

Please note that this declaration is only valid for prime products, natural.

If you have any further questions, please do not hesitate to contact us.

With best regards
Universal Polythex Kunststoffe GmbH