

Food Contact Statement

We hereby declare that regarding the composition of the product manufactured and identified as:

Polystyrene Virgin

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 legislation:

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 : 25mg/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.

Dual use (substances listed as food additives as well food contact additives)

The above mentioned product does not contain substances which can be classified as dual use substances.

Regulation (EC) No 1935/2004, Article 3

We declare 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, we can state that there is a system in place which enables the control of the material stream in our production and to trace the materials back to our upstream suppliers.

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

² Amendments of Regulation (EU) No 10/2011: Regulations (EU) No 321/2011, No 1282/2011 and No 1183/2012.

Good Manufacturing Practice 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, 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, 1 kg of food in contact with 6dm² of packaging, 250 Nm thickness). We are 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 above-mentioned restrictions/limitations (OML, SML, etc.). 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 thereof.

US FDA Status

The composition of the product complies with the requirements of the 21 CFR 177.1640 "Polystyrene and rubber modified polystyrene".

European Standard EN71 - Safety of Toys

European Standard EN71 deals with the safety of toys, and Part 3 sets limits on the migration of antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy material.

The supplier does not deliberately add any of these metals or their chemical compounds to the above grade. To the best of our knowledge these metals are also not present in the raw materials used to manufacture this polymer.

Therefore we have no reason to believe that the above product would not comply with the requirements of EN71-3:2002.

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 Regulation (EC) No 219/2009 is met. Please note that this declaration is only valid for prime products manufactured within the European Union.

Universal POLYTHEX Kunststoffe GmbH

(This document is created automatically and valid without signature.)