

EU (European Union) Food Contact Regulatory Compliance Statement

Company Identification

Orbi-Tech GmbH, Motlkestrasse 25, 42799 Leichlingen, Germany

We hereby declare that for the composition of the products manufactured and identified as

HiPS

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].

Finished products fabricated with the above products 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

SML1: butadiene (CAS No. 106-99-0): ND (detection limit of 0,01 mg/kg); with a specific restriction for this substance of 1 mg/kg in final product.

SML2: 25 mg/kg, zinc stearate group, CAS No. 557-05-1, expressed as zinc, applies (Ref. No 24550, stearic acid).

SML3: octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CAS No. 2082-79-3): 6 mg/kg (Ref. No 68320); 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.

SML4: 2,4-Bis(octylthiomethyl)-6-methylphenol (CAS No. 110553-27-0): 5 mg/kg (Ref No 40020, expressed as the sum of the substances Ref Nos 40020 and 38940) ; 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 Amendments of Regulation (EU) No 10/2011: Regulations (EU) No 321/2011 and No 1282/2011.

Dual use

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

The above mentioned products do 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 products 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.

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 SML should not be exceeded on the use of the above mentioned materials in food contact applications. This refers to standard conditions of use (= 10 days, 40°C, 1kg of food in contact with 6dm² of packaging, 250 µm 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 products 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 products complies with the requirements of FDA Regulation 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. Orbi-Tech does not deliberately add any of these metals or their chemical compounds to the above polystyrene grades. To the best of our knowledge these metals are also not present in the raw materials used to manufacture these polymers. Therefore we have no reason to believe that the above polymers would not comply with the requirements of EN71.3.

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.

Other Information

Orbi-Tech GmbH makes no warranties, express or implied, concerning the suitability of the above HiPS grades for use in any medical device and pharmaceutical applications.

The information above refers to the state of the laws at the date of issue. This confirmation expires after 12 months or in the case of regulatory changes. When new statements are published on the internet portal, the former statements automatically become void. In your own interest please regularly check the information on the internet portal.

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