

Food Contact Statement

BendLay

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

BendLay

the basic polymer chemically consists of styrene-butadiene block copolymer 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].

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 : acrylic acid, 2,4-di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl)phenyl ester (CAS No. 123968-25-2; FCM No. 762): 5 mg/kg food; 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 3 : 0,6 mg/kg, lithium from lithium salts (Annex II).

SML 4 : 25mg/kg, zinc from zinc salts (Annex II).

Worst case calculations with respect to the amounts added by Styrolution show that the SML of zinc is safely ensured.

The observance of any given limitation must be especially monitored for food with high fat content.

Dual use additives (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.

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.

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.

US FDA Status

The composition of the product complies with the requirements of FDA Regulation 21 CFR 177.1640 "Polystyrene and rubber-modified polystyrene". It can be used in contact with all food types under conditions of Use A through H as described in Table 1 and 2, of 21 CFR 176.170 (c).

The observance of any given limitation must be especially monitored for food with high fat content.

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 GmbH 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.

For notice: Appropriate processing conditions for the articles have to be applied. The suitability of the articles for the application concerned, including their effect on smell and taste of the food, and observance of any given limitations (for example overall migration, specific limits and other analytical requirements) must be tested and ensured in each case by the person who introduces the articles into circulation.

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. It is the responsibility of those to whom we supply our products to ensure that any proprietary rights and existing laws and legislation are observed. The statement provided is exclusively for our customers and respective competent authorities. It is not intended for publication either in printed or electronic form (e.g. via internet) by others. Thus, neither partial nor full publication is allowed without written permission.