

Declaration of Compliance

Name of the business operator

issuing the declaration of compliance: (1) BioTech USA Kft.
1033 Budapest Huszti út 60

**Name of the business operator
which manufactures plastic materials
from intermediate stages of
their manufacturing: (2)**

Huniplast Kft
1182 Budapest Csörszárók u. 14,
registered site: 2220 Vecsés, Almáskert u.16.

Name of the plastic products (3): Wave shaker 600ml

PP Shaker cup (CAS:9003-07-0), PE shaker lid (CAS:9002-88-4), PP cap (CAS:9003-07-0), PP shaker screen (CAS:9003-07-0),
Only original materials were used during manufacturing and no recycled materials were used for the products.

Date of the Declaration (4): 16.08.2021

**Compliance with Directive (EC)
No 10/2011 and (EC) No 1935/2004**

(5):

In accordance with Commission Regulation (EU) No 10/2011 and Regulation (EC) No 1935/2004, the products are in compliance with the requirements regarding contact with food.

The manufacturing conditions of the product are in compliance with the requirements of Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The product, described in Section 3 of this Declaration of Compliance, is in compliance with organoleptic requirements regarding food contact materials not yet in contact with food and intended for direct use by consumers.

**No substances which are subject
to restrictions are used (6):**

Phthalates such as DEHP, other restricted chemicals such as BPA and BPS are not used when manufacturing polymers, therefore it is expected that such substances will not be present in the products.

All "positive lists" of materials and additives used during manufacturing are in compliance with the requirements of the European Union regarding plastics (EU Plastic, Commission Directive No 10/2011).

Based on information provided by our raw material suppliers, we hereby declare that the total concentration of lead, cadmium, hexavalent chromium, etc. is lower than 100 ppm, therefore, the product is in compliance with the requirements of Regulation (EC) No 2023/2006 (GMP), with Directive 2004/12/EC amending Directive 94/62/EC on packaging and packaging waste regarding heavy metal content.

Substances which are subject to restrictions and their specific migration (7):

No dual use additives were used during the manufacturing of the product.

Direct contact with food (8):

Max. 40 ° C
Maximum contact time: 24 hours

Non-food contact:

Min. -20 ° C
Max. temperature: + 80 ° C
Ratio of food contact surface area to volume

600 ml	1:19
500 ml	1:18
400 ml	1:17
300 ml	1:13
200 ml	1:12
100 ml	1:10

may be stored in the freezer
microwave-safe.
dishwasher-safe

General:

The products are suitable for storing dry and liquid foods. This declaration shall be effective as long as the materials used for the product or the legislations are not changed and it is based on the information provided by the manufacturer of the materials used.

Functional barrier (9): The product does not have a functional barrier.

Lévai Bálint
CEO of BioTech USA Ltd.

Budapest, 23.01.2024

Signature:


BIOTECHUSA Kft.
1033 Budapest, Huszti út 80.
Adószám: 25114681-2-44
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