Prohlášení o shodě

pro výrobky z plastů určené pro styk s potravinami

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Produkt

Polystone® M AST + FDA černý stisknuto

We herewith confirm that the semi-finished product made from the material mentioned above is in compliance with the requirements of the following regulations:

- (EC) No 1935/2004 of the European Parliament and the Council dated 27th October 2004 applicable for materials and goods destined to come into contact with foodstuffs and for revocation of the directives 80/590/EEC and 89/109/EEC, Gazette of the European Communities L 338/4 dated 13th November 2004, poslední změna článkem 5 nařízení (EU) 2019/1381 ze dne 20. června 2019, Věstník Evropských společenství L 231/1 ze dne 6. září 2019, čl. 3 odst. 1 písm. a) a b).
- Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFGB) in the version of the notification of 15. září 2021 (BGBl. Ip. 4253), poslední změna článkem 7 směrnice ze dne 27. září 2021 (BGBl. P. 4530), §§ 30 a 31.

Furthermore, the product meets the requirements of

- (EC) No 10/2011 of the Commission dated 14th January 2011 on plastic materials and articles to come into contact with food, Gazette of the European Communities L 21/1 dated 15th January 2011, last amendments by Commission Regulations (EU) No 1282/2011 dated 28th November 2011, (EU) No 1183/2012 dated 30th November 2012 and (EU) No 202/2014 dated 3rd March 2014

regarding the composition and the migration behaviour.

The manufacturing of the product mentioned above is carried out according to the method „Good Manufacturing Practice“ (GMP), corresponding to the regulation (EC) No 2023/2006 of December 2006 applicable for the good manufacturing practice for materials and goods destined to come into contact with foodstuffs. According to the regulation (EC) No 1935/2004, the traceability of our products is guaranteed at all levels and is carried out by means of the production number inscribed on the product label or the accompanying documents.

Testing conditions for migration tests based on the application

The product was tested according to the methods for “examination of utensils“ by means of several samples, according to the regulation B 80.30, 1 to 3 (EC) of the Official List of testing procedures according to § 64 LFBG (Germany), as well as the series of

standards EN 1186, EN 13130 and CEN/TS 14234 “materials and goods in contact with foodstuffs – plastics“.

According to the general rules for migration tests, the total migration and the specific migrations of individual substances were determined by using food simulants and pre-defined testing conditions (time/temperature). The overall migration as well as the specific migration does not exceed the legal limits set out in directive (EC) No 10/2011 when used as specified in table 1.

Tabulka 1 - Určení migračních charakteristik

Testování simulantu	Podmínky testování	Určený ke styku s potravinami
3 weight % acetic acid	2h, 100°C	Direct contact with foodstuffs of all kinds.
10 vol.% ethanol	2h, 100°C	
Isooctan as substitute for fat	6h, 60°C 2d, 20°C	

Ratio of the surface in contact with the foodstuff to volume (S/V), used to determine the compliance of the material:

6 dm^{-1}

Information on substances used or their degradation products for which Annexes I and II of Regulation EU 10/2011 contain restrictions and / or specifications

CAS Name	Omezení
	-

OML = total migration (OML) <10mg / dm^2
SML = specific migration limit in food or in food simulant
SML(T) = Total Specific Migration Limit
QMA = max. permitted quantity in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs.

Dual Use

The following substances, which are also approved as food additives („Dual use“), may be contained in the product mentioned above (EC directives 89/107/EEC, 95/2/EC):

CAS Name	Omezení
	-

(as far as information concerning this point is included in the conformity documents made available by the raw material producer.)

NIAS (non-intentional added substances)

As part of the conformity assessment, studies on non-intentional added substances (NIAS) were performed by means of GC-MS screenings on representative selected test samples.

Nebyly zjištěny žádné nečistoty ani vedlejší reakce nebo produkty rozkladu (NIAS).

CAS Name	Podklad pro hodnocení	Limitace
	-	-

Functional Barrier

Use of a functional barrier acc. Regulation (EU) No 10/2011 Article 3: None

Result

The quality Polystone® M AST + FDA černý stisknuto can be used safely for the manufacture of finished products for companies which are preparing and processing foodstuffs. The finished products may stand in přímo contact with all types of food as far the quality Polystone® M AST + FDA černý stisknuto is concerned.

It is important that the above-mentioned contact times and temperatures are not exceeded regarding the Regulation (EU) No 10/2011.

General Information

This declaration serves as a supporting document for the downstream user. Our semi-finished materials or cuts from these semi-finished materials are products from intermediate stages of production in accordance with Regulation (EU) 10/2011, Article 15 and are not consumer goods in the sense of the Bedarfsgegenständeverordnung (§ 2) and the Lebensmittel- und Futtermittelgesetzbuchs (§ 2 Abs. 6 Satz 1 Nr. 1), as well as Regulation EC/1935/2004, Article 1, Para. 2.

The formulations of our materials listed in the declarations of conformity have been subjected to extensive migration tests with various simulants in accordance with EU 10/2011 at an independent accredited institute. The tests were carried out on mechanically processed samples of our semi-finished products.
Furthermore, it has been assured that generally only such raw materials are used for the material where the appropriate verifications of suitability (supporting documents) have been provided by the raw material supplier or the raw material supplier discloses its ingredients to a suitable third party (testing institute/laboratory) by means of a confidentiality agreement.

The material is basically suitable for use in contact with food under the aforementioned conditions. However, since we do not know the conditions of use of the finished articles, it remains the responsibility of the customer to determine the suitability of the plastic articles (consumer goods) produced from or with our products for their intended use or rather under the respective conditions of use (contact time, contact temperature for the respective type of foodstuff). In addition to the general suitability for use of the material (e.g. chemical resistance to the cleaning agent used), such responsibility also includes observation of the migration limits in the event the actual contact conditions exceed or deviate from the "intended food contact" laid down in our declaration of conformity.

The aforementioned products are not suitable for medical or dental applications.

Organoleptic Testing:
Organoleptické testování Haren/Lahnstein

Liability claims against the issuer of this declaration of conformity related to damage of a material, immaterial or ideal nature and caused by the usage or non-usage of the information offered or by the usage of defective and/or incomplete information are excluded on principle.

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