

DECLARATION OF CONFORITY FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFF

Hereby, **VMECA** declares that, in the conditions of use foreseen and foreseeable, and in the condition in which are market, the articles

“Vacuum Pad Stopper for foodstuff”,

It is suitable for repeated use in contact with food, and storing long-term in room temperature (15°C), including heating it up to 40°C for up to 10 days. (Min operation temp: -100°C)

are compliant

to all relevant legislative dispositions, with specific reference to the European and Extra-European Community legislations:

- (EC) 1935/2004 Regulation and subsequent updates and amendments;
- (EC) 10/2011 Regulation and subsequent updates and amendments;
- FDA (USA) Regulation, Title 21, Federal Regulation Code (CFR) 177.2600

The Polycarbonate material is manufactured with the following materials and substances:

- Carbonic acid, diphenyl ester, polymer with 4,4'-(1- methylethylidene)bis[phenol]

We declare that: the material contains substances subject to restrictions in the aforementioned legislations, and reflects the global migration limits in the following test conditions:

- 1. Commission Regulation (EU) No 10/2011 with Amendments and Article 3 of European Regulation No. 1935/2004.
- German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments.

1. European Commission Regulation (EU) No 10/2011 with Amendments

a) Plastic – Overall migration

Method: With reference to EN 1186-1:2002 for selection of conditions and test methods; EN 1186-3:2002 aqueous food simulants by total immersion method; EN 1186-14:2002 Substitute test

Simulant Used	Test Condition	Result (mg/dm ²)	Detection Limit (mg/dm ²)	Permissible (mg/dm ²)
3% Acetic Acid(W/V) Aqueous Solution	40 °C for 10 days	N.D	3.0	10
95% Ethanol(V/V) Aqueous Solution	40 °C for 10 days	N.D	3.0	10
Isooctane	20 °C for 2 days	N.D	3.0	10
Comment	--	PASS	--	--

1. mg/dm = milligram per square decimeter

2. °C = degree Celsius

3. N.D = Not Detected

4. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of January 2011 with amendments.

b) Plastic – Specific migration of Heavy metals

Method: With reference to EN 13130-1:2004. Analysis was performed by ICP-MS / ICP-OES.
Simulant Used: 3 % acetic acid (w/v) in aqueous solution Test Condition: 40 °C for 10 days

Test Item	Result (mg/dm ²)	Reporting Limit (mg/dm ²)	Permissible (mg/dm ²)
Specific Migration of Barium	N.D	0.3	1
Specific Migration of Cobalt	N.D	0.01	0.05
Specific Migration of Copper	N.D	0.3	5
Specific Migration of Iron	N.D	0.3	48
Specific Migration of Lithium	N.D	0.5	0.6
Specific Migration of Manganese	N.D	0.3	0.6
Specific Migration of Zinc	N.D	0.5	5
Specific Migration of Aluminium	N.D	0.1	1
Specific Migration of Nickel	N.D	0.02	0.02
Comment	PASS	--	--

1. mg/kg = milligram per kilogram of foodstuff in contact with
2. °C = degree Celsius
3. N.D -= Not Detected.
4. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of January 2011 with amendments.

c) Specific Migration of Bisphenol A

Method: With reference to CEN/TS 13130-13:2005. Analysis was performed by LC/MS/MS
Test Condition: 40 °C for 10 days

Test Item	Result (mg/kg)	Detection Limit (mg/kg)	Permissible Limit (mg/kg)
Specific Migration of Bisphenol A (3% acetic acid) (w/v) in aqueous solution	N.D	0.01	0.05
Specific Migration of Bisphenol A (95% Ethanol) (V/V) in aqueous solution	0.01	0.01	0.05
Comment	PASS	--	--

1. mg/kg = milligram per kilogram of foodstuff in contact with
2. N.D -= Not Detected.
3. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of January 2011 with amendments.

d) Specific Migration of Primary Aromatic Amine

Method: With reference to EN 13130-1:2004. Analysis was performed by UV-vis Spectrophotometer. Simulant Used: 3% acetic acid (w/v) in aqueous solution Test Condition: 40 °C for 10 days

Test Item	Result (mg/dm ²)	Reporting Limit (mg/dm ²)	Permissible (mg/dm ²)
Specific migration of Primary Aromatic Amine	N.D	0.002	0.01
Comment	PASS	--	--

1. mg/kg = milligram per kilogram of foodstuff in contact with
2. °C = degree Celsius
3. N.D -= Not Detected.
4. Permissible Limit is according to Commission Regulation (EU) No 10/2011 of January 2011 with amendments.

2. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with Amendments

a) Sensorial examination of odour and taste

Test Method: With reference to DIN10955: 2004

Migration condition: 40 °C for 10 days

Test Simulant: Water

The number of panelists: 6

Test Simulant	Test Item	Result	Maximum Permissible Limit
Water	Sensorial examination odour	0.5	2.5
	Sensorial examination taste	1.0	2.5
Comment		PASS	--

1. Intensity scale (rounded at 0.5):
 - 0 – no perceptible difference
 - 1 – just perceptible difference
 - 2 – slight difference
 - 3 – marked difference
 - 4 – strong difference
2. Permissible Limit is according to LFGB with its amendment, Section 30 and 31, and Regulation (EC) No 1935/2004 of The European Parliament and of the Council of 27 October 2004.

The article is suitable for contact:

- **With all types of foodstuff**

The company declares the technological suitability of the product for the purpose of which it is intended.

To support what above stated, the company declares to have available to (indicate customer) and the competent Authority:

- Other supporting documentation required in accordance with Reg. FDA (USA) Regulation, Title 21, Federal Regulation Code (CFR) 177.2600
- Other supporting documentation required in accordance with Reg. (EC) 1935/2004 art. 16 paragraph1.

This declaration is valid from the date shown below and must be replaced when there are substantial changes in the production of the material that can change certain essential requirements for compliance or when the aforementioned legislative references are modified in order to require a new verification for compliance purposes.

The company VMECA is equipped with a quality management system certified ISO 9001_2015.

Date : 17 NOV. 2021

Signature



S. D. Park / Director of R&D Dept.