

Sartorius Stedim Biotech GmbH, 37070 Göttingen

To Whom It May Concern

November 12, 2024

Declaration of Compliance with Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

The following **Filter Cartridges with Polypropylene (PP) membranes**,

Sartopure PP3 Cartridges (0.45 µm, 0.65 µm, 1.2 µm, 3.0 µm, 5.0 µm, 8.0 µm, 20 µm, 50 µm, 100 µm)

(Order code 5052_06P_)

(Order code 5052_05P_)

(Order code 5052_03P_)

(Order code 5052_02P_)

(Order code 5052_42P_)

(Order code 5052_01P_)

(Order code 5052_20P_)

(Order code 5052_50P_)

(Order code 5052_98P_)

Sartopure PP3 Mini Cartridges (0.65 µm, 1.2 µm, 3.0 µm, 5.0 µm, 8.0 µm, 20 µm)

(Order code 5051505P_)

(Order code 5051503P_)

(Order code 5051502P_)

(Order code 5051542P_)

(Order code 5051501P_)

(Order code 5051520P_)

Sartopure IND Cartridges (0.45 µm, 0.65 µm, 1.2 µm, 3.0 µm, 5.0 µm, 8.0 µm, 20 µm, 50 µm)

(Order code 5502_06P_)

(Order code 5502_05P_)

(Order code 5502_03P_)

(Order code 5502_02P_)

(Order code 5502_42P_)

(Order code 5502_01P_)

(Order code 5502_20P_)

(Order code 5502_50P_)

Sartovent P Cartridges (0.2 µm)

(Order code 5521607P_)

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distributed by Sartorius Stedim Biotech GmbH, comply with the requirements set forth in the Regulation (EC) No 1935/2004 of the European Parliament and of the Council, Commission Regulation (EC) No 2023/2006 and Commission Regulation (EU) No 10/2011 of January 14, 2011, regarding plastic materials and articles intended to come into contact with food. They also adhere to subsequent amendments and corrections up to Commission Regulation (EU) No 2023/1627 of August 10, 2023.

Specification of the intended use or limitations

The above-mentioned products may be used safely for the industrial filtration of aqueous, acidic and light alcoholic foodstuffs up to 50% (v/v), at temperatures of 40°C or below under consideration of the repeated use of the products. According to the migration tests performed by an accredited laboratory (DIN EN ISO/IEC 17025), the products may be used safely for a calculated minimum flow rate of 10 L per hour. An initial pre-flushing according to 'Instructions for use' is mandatory prior to use.

Substances with limits and restrictions as listed in Regulation (EU) No 10/2011

The Regulation (EU) No 10/2011 specifies the limit of 60 mg/kg food or simulants or the limit of 10 mg/dm² surface as the maximum overall migration limit (OML) from the finished plastic food contact material or article. For each substance subject to specific migration, the migration of the substance should not exceed its limit (SML).

Based on raw material supplier information, the products contain some substances which are subject to restrictions and/or specifications as defined in Annex I of (EU) No 10/2011 and may contain traces of heavy metals or primary aromatic amines (PAAs) which are regulated with a specific migration limit according to Annex II of the Plastics Regulation (EU) No 10/2011.

The compliance with the legal provisions of Annex I and II of Regulation (EU) No 10/2011 was examined on worst-case calculations or migration testing according to Regulation (EU) No 10/2011 by an independent accredited laboratory.

When used as the specified intended use, the overall migration as well as the specific migration values (include Annex I and Annex II: Heavy metals, Primary aromatic amines) do not exceed the legal limits set out in Regulation (EU) No 10/2011.

Dual use additives

The following dual use additives subject to restrictions in food as defined in (EC) No 1333/2008 and (EC) No 1334/2008 may be present in the above referenced products:

- Calcium salts of fatty acids (CAS 1592-23-0) (E 470a)

Due to the overall migration limit (10 mg/dm² or 60 mg/kg), it seems very unlikely that a food additive used as a plastic additive will compromise the compliance with the regulatory threshold for this additive in the food product. In case an additive is used in a quantity approaching the maximum level in food, we will discuss this situation with the producers of the raw material.

Organoleptic properties

An organoleptic test according to DIN 10955 with three times contact to drinking water for 30 min at 23 °C ± 2 °C results in no undue sensory deviation. Owing to the different applications, it is the responsibility of our customers to perform further appropriate organoleptic tests in combination with the used food.

Note:

This EU DoC is supported by conformity declarations received from our raw material suppliers and migration tests carried out by third parties. This document is valid starting from the above issue date for two (2) years unless significant modification in our products formula structure or in the case of legal changes become effective. Please ask for a new declaration if needed. In addition, it is the responsibility of our customers to check that their use of our product(s) is safe, and according to the information given in this document, lawful and technically suitable.

Sincerely
Sartorius Stedim Biotech GmbH

BPS Regulatory Compliance
Manager Regulatory Affairs

Signiert von:
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