

Sartorius Stedim Biotech GmbH, 37070 Göttingen

To whom it may Concern

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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

Sartovent P Caps 0.2 µm
(Order code 5521607Pxx)

distributed by Sartorius Stedim Biotech meet the requirements laid down in the Framework Regulation (EC) No 1935/2004 and Commission Regulation (EU) No 10/2011 of 14th January 2011 on plastic materials and articles intended to come in to contact with food, and subsequent amendments and corrections up to Commission Regulation (EU) No 2020/1245 of 2th September 2020.

Specification of the intended use or limitations

The intended use of these products is the industrial filtration of aqueous, acidic and light alcoholic foodstuffs up to 50% (v/v) at a maximum contact temperature of 40 °C. According to the migration tests performed by an accredited laboratory (EN ISO 17025), the products may be used safely for a calculated minimum flow rate of 10 L per hour.

Substances with limits & 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.

Overall migrations and specific migrations of substances with Specific Migration Limits (SML), was tested by an independent accredited laboratory.

The following substances found in the above-mentioned products are subject to restrictions and/or specifications:

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Registered Office:
Göttingen
Local Court of Registration:
Amtsgericht Göttingen
HRB No. 200266

Managing Directors:
Uwe Becker,
Bettina Berendsen

Chairman of the Supervisory
Board:
Dr. Joachim Kreuzburg

Substance name	FCM no.	CAS no.	SML [mg/kg]
N,N-Bis(2-hydroxyethyl)alkyl (C ₈ -C ₁₈)amine	19	-	1.2
N,N-Bis(2-hydroxyethyl)alkyl (C ₈ -C ₁₈)amine hydrochloride	20	-	1.2
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	433	2082-79-3	6
Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphate	652	26741-53-7	0.6
1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	661	27676-62-6	5
Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino]	740	71878-19-8	3
9,9-Bis(methoxymethyl)fluorene	779	182121-12-6	0.05

Note: These products contain some additional proprietary substances subject to specific migrations limits or other restrictions, for which the identity may be disclosed to a certified testing laboratory for performance of necessary tests, subject to a non-disclosure agreement.

Based upon the intended conditions of use, the overall migration as well as the specific migration values do not exceed the legal limits.

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:

Substance name	E number
Calcium salts of fatty acids	E 470a

Organoleptic properties

An organoleptic test with 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.

Sincerely
Sartorius Stedim Biotech GmbH
Site Quality Manager

Manager of Product Compliance,
Separation Technologies



Dr. Anna Vreemann



Dr. Christian Hoffmann