

Overensstemmelseserklæring

September 2019



UNIKA DANMARK A/S bekræfter hermed at nedenstående produkt
PTFE Fluteck 1000 + 1500 er i overensstemmelse med de nævnte forordninger.

fluorseals^{spa}®

prodotti in p.t.f.e.

24064 Grumello del monte (Bg) Italia - Via Tribolina, 20/22

Tel. +39 035 4492811 - Fax +39 035 831410

www.fluorseals.it - info@fluorseals.it

We certify that our fluteck™ P1000 and fluteck™ P1500 products made of virgin pte resin, that we buy from the most reliable worldwide producers, are suitable to get in contact with foodstuffs, according to the following requirements:

EC Regulations:

- Regulation 1935/2004/CE;
- Regulation 1895/2005/CE;
- Regulation 10/2011/UE – 2023/2006/UE and following revisions; after being approved in the national laws;

Italy Regulations:

- Department Decree law 21/03/1973 and following revisions;
- DPR 777/82 and following revisions ;

USA Regulations:

FDA, Food and Drug Administration, Department of Health and Human Services, Code of Federal Regulations 21 CFR Ch. 1; USA regulations sections 177.1550 (a) (1) and (b)- Perfluorocarbon Resins;

We certify that our material does not contain substances subjected to restrictions in the above mentioned regulations and it complies with the global migration limits, at the following conditions (10/2011/UE):

- Food simulant: food simulant B (acetic acid 3% p/v in aqueous solutions);
- Condition of contact: 4 hours at 100° C reflux temperature (repeated use);
- Food simulant: food simulant D (ethanol 50% V/V in aqueous solutions);
- Condition of contact: 4 hours at 100° C reflux temperature (repeated use);
- Food simulant: food simulant D2 (vegetable oil);
- Condition of contact: 2 hours at 175°C – repeated use);
- Food simulant: food simulant E (modified polyphenylene oxide);
- Condition of contact: 5 minutes at 240° C – repeated use);

Migration test was carried out by Total Immersion.

LOD (limit of detection): 5 mg/dm².



Company Quality System UNI EN ISO 9001:2008 cert. CISQ/IIP N°061 first issue 1994

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Determination of the overall migration

Verification of the suitability of articles and materials to be employed in contact with foodstuffs, according to D.P.R. 777 dated 23/08/1982, D.L. 108 dated 25/01/1992, D.M.34 dated 21/3/73 European Directives: 82/711/EEC GUCEE L 297 dated 23/10/82, 85/572/EEC GUCEE L 372 dated 31/12/1985, 93/8/EEC GU L90

dated 14/04/1993, 97/48/EC GUCE L 222 dated 12/8/97.

Regulations 1935/2004/EC GUCE L 338 dated 13/11/04 and 1895/2005/EC GUCE L 302 dated 19/11/2005.

Regulation 10/2011/EC. UNI EN 1186 1÷15:2003.

The ratio between exposed sample surface (dm²) and Simulant volume has to be included from 0,5 to 2.

Specific Migration of BA, CO, MN, ZN, CU, FE, LI (*)

Determination of the specific migration of Ba, Co, Mn, Zn, Cu, Fe, Li according to Reg. EC 10/2011 from the tested material into the stimulants by ICP (Inductively Coupled Plasma) technique with OPTIMA 4300DV Perkin Elmer instrument. The quantitative evaluation was carried out by external calibration of the elements in the same liquid simulants.

SML Ba: 1 mg/kg;

SML Co: 0.05 mg/kg;

SML Mn: 0.6 mg/kg;

SML Zn: 25 mg/kg;

SML Cu: 5 mg/kg;

SML Fe: 48 mg/kg;

SML Li: 0.6 mg/kg;

LOD: 0.02 mg/kg (for every element).

Determination of the specific migration of tetrafluoroethylene

The determination of tetrafluoroethylene specific migration in the three previously described simulants has been carried out after conditioning at the previously described conditions by Head space Analysis using a GC-MS (HO7694/HP6890-5973). Quantification has been obtained using a external calibration of tetrafluoroethylene in previously described simulants.

Name of the substance CAS number FCM number Limitations/Specification Determined Value

Tetrafluoroethylene 116-14-3 281 SML 0,05mg/kg <0,05 mg/Kg

Olfactory organoleptic test according to UNI 10192

The olfactory scoring test is a evaluation of the odor, measured with a 5 point scale. Each judge is asked to smell the samples. They are then asked to give a mark to each flask:

0: no perceivable smell

1: little perceivable smell, very difficult to define;

2: weak but identifiable smell;

3: strong smell;

4: very strong smell



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The final result is expressed with the average value of the scores given by each judge, coupled with the standard deviation.

Test conditions:

time of conditioning : 18 hours

temperature of conditioning : 55 ± 1 °C

n° judges : 8

quantity of sample: 10 g

volume of container: 500 ml

A potential organoleptic impact is to be acknowledged to the sample if the score (average value + standard deviation) is ≥ 3 .

In the chosen test condition the sample fluteck™ P1000 and fluteck™ P1500 material are suitable to be used in contact with aqueous, acidic, alcoholic (till 10% V/V) and oily or fatty foodstuffs for which simulants A, B, C and D2 are used.

The user of the material, intended for contact with food, has the responsibility to inform the manufacturer if there are any restrictions related to the compositional features in the foodstuffs (presence of additives and aromas).

Furthermore, the user must verify that the finished item, machined from the semi-finished product, would be technically suitable for the requested application and it may not cause any modification to the organoleptic properties of the foodstuff. The technological suitability of the material, it is assigned to, must be guaranteed.

For each foreign country market, where the items are introduced into, it is responsibility of the user to determine whether both material than items would comply with the applicable laws and regulations.

This declaration is valid starting from the below date. It could be replaced, in case there will be substantial changes in the production of material, able to change the essential requirements for compliance purposes, or in case the above mentioned regulations, will be modified and updated. In such events, a new verification for compliance will be requested.

This statement has however a validity time up to 24 months.

fluorseals S.p.A.

QA. Dpt.

Date: 09/2019



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