

DECLARATION OF COMPLIANCE SUPRApak™ Retrofit Adaptor

Part Number

SPMRTF2
Table 1

This is a guide to the part numbering structure only. For specific options, please contact Pall.

Table 1 : Housing Type

| Code | Housing Type |
|------|--------------|
| 1 | 1 high |
| 2 | 2 high |
| 3 | 3 high |
| 4 | 4 high |

SUPRApak Type 2 Retrofit Adaptors are intended to allow SUPRApak modules to fit into certain types of lenticular housings for cold filtration of foodstuffs. These adaptors may be used to support fit of SUPRApak modules during filtration of non-alcoholic as well as alcoholic beverages.

An initial flush is recommended prior to use.

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SUPRApak Type 2 Retrofit Adaptors

Components

| | |
|----------------|--|
| Metal parts: | Stainless Steel (316L) |
| Plastic parts: | Polypropylene with grey colorant |
| Seals: | Silicone elastomer, EPDM rubber and PTFE thermoplastic |

Declaration

Europe

The SUPRApak Type 2 Retrofit Adaptors meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

- Our suppliers state that all materials and raw materials used in the manufacture of the polypropylene parts employed in the SUPRApak retrofit adaptors are in compliance with Annex I of Commission Regulation (EU) Number 10/2011 and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs.

Migration testing of the polypropylene components was carried out in after flushing and in flow conditions:
Simulant B (3 % Acetic acid) for 24 hours at 40 °C (104 °F)
Simulant C (20 % Ethanol) for 24 hours at 40 °C (104 °F)
Simulant D2 for 24 hours at 40 °C (104 °F)
- The stainless-steel materials of construction, of the wetted parts are purchased to ANSI 316L definitions. Materials meeting ANSI 316 L definitions are consistent with the requirements of Arrete of January 13th 1976 for l'acier inoxydable.
- Representative samples of the grades of stainless steel materials of construction, after exposure to their typical manufacturing process, passed the requirements of OML and SML requirements in respect of Italian Regulations DM 21/03/1973 and its amendments including Decreto 11 novembre 2013, n. 140 and Decreto 6 agosto 2015, n. 195.
- Our suppliers state that the Silicone Elastomeric seals materials are compliant to the BfR section XV specification for this material.

Note:

This product contains Polypropylene that is subject to Specific Migration Limit (SML) requirements.
This product contains Calcium Stearate, which is approved as a direct food additive.

USA

The following materials of construction meet the FDA requirements for food contact as detailed in US Code of Federal Regulation 21 CFR 170-199 in that:

- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- PTFE to 21 CFR section 177.1550 (Perfluorocarbon resins)
- Silicone Elastomeric seal materials Ethylene Propylene Rubber seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

Process Quality System

Site of Manufacture: Pall Manufacturing UK Ltd, Portsmouth, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Manufacturing UK Ltd, Portsmouth is certified to ISO 9001:2015.

Pall Manufacturing UK Ltd confirm that the product manufacturing environment, for the above product at our Portsmouth site, is in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

Supplied in Europe by

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