

Letter of conformance FOOD SAFE - EC1935/2004, EC 10/2011 conformity

Garlock GmbH
Falkenweg1
41468 Neuss - GERMANY

We hereby confirm,

our virgin PTFE Liner material which is used in different product series, namely GAR-SEAL®, MOBILE-SEAL®, STERILE-SEAL®, TOXI-SEAL® complies with the following regulations and laws in its current version as listed below:

- European Regulation (EC) No. 1935/2004*, with relevant requirements of regulation (EC) No 10/2011
- European Regulation (EC) No. 2020/1245*, including the requirements of changed Appendix I, II, IV and V
- Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and animal feed code - LFGB) with the relevant requirements of the German Consumer Goods Ordinance
- BfR memorandum on the examination of high polymers No.62
- FDA 21 CFR 177.1550 They meet ingredient and extract requirements.

The overall migration as well as the specific migration are below the legal limit values and in case of an application in accordance with the specifications. Compliance with the overall migration limits for all type of food testing to simulant A, B and D2 has been performed (tests up to and including OM7 were performed).

All Monomers and Additives which are used during production are listed within Annex I aof EC10/2011, no "Dual Use" additives are added. Above mentioned material is fully synthetic and only the following Substances with a limitation and/or specification are employed in the product mentioned above:

Substance	Effective	Limitation (SML)
Tetrafluorethylen(CAS 116-14-3)	not detectable	smaller 0,5 mg/kg
Squalen	0,005 mg/dm ²	smaller 60 mg/kg
Alkan	0,0006 mg/dm ²	
Fatty acid ester	0,006 mg/dm ²	

Thus, the above mentioned material may be used safely in the production of any kind of foodstuffs and may stand in direct contact with dry, aqueous, acid and fatty foodstuffs.

* This compression packing Style also is used within process and industries, which are not rated to EC 1935/2004 and only is delivered with traceability under request within ordering process.

Specification regarding the intended use:

- Kind of foodstuffs or procedure for which the material is suitable:
 - o beverages: non-alcoholic and alcoholic drinks up to undenaturated ethyl alcohol
 - o corn, cereal products, pastry products, biscuits, cakes and other baked goods
 - o chocolate, sugar and products obtained from it, confectioneries
 - o fruit, vegetables and products obtained from it
 - o fats and oils
 - o animal products and eggs
 - o dairy products
 - o Various products: vinegar, fried or roasted foodstuff, preparation for the cooking of soups, stocks (liquid, solid or powder), sauces, mustard, sandwiches, ice cream, dried foodstuffs, deep-frozen foodstuffs, concentrated extracts with an alcohol content of at least 6%, cacao, coffee, aromatic herbs, spices and condiments in a natural state and in an oily medium
- Duration and temperature of the treatment and storage when in contact with the foodstuff
 - o High temperature applications with dry, aqueous and fatty foodstuffs up to 2 hours at temperatures of up to 175°C as well as long-term storage at room temperature and below
- Ratio between the surface in contact with the foodstuff and the volume, based on which the compliance of the material or article was determined.
 - o 6 dm² surface / 1 kg foodstuff

This letter of conformance represents the latest technical standard and has a unlimited validity. It will be renewed in case of significant changes in composition or production that influence the migration of the material or if new scientific evidences emerge.

Garlock GmbH
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Neuss, 09th August 2022, R. Kulesa, Senior Application Engineer

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