

Garlock Sealing Technologies

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FOOD CONTACT DECLARATION Garlock Gylon® Style 3549 Lip Seal Material

<u>Declaration of Compliance to Regulation (EC) No. 1935/2004 on Materials and Articles Intended</u> to Come in Contact with Food:

Garlock Gylon® Style 3549 Lip Seal Material may be used for repeated use in the production of all types of food contact up to 175°C as it complies with the regulatory and legislative requirements of (EC) No. 1935/2004 and the following:

- (EC) No. 2023/2006 on Good Manufacturing Practices (GMP) for Materials and Articles intended to come into contact with food:
- 2) (EU) No. 10/2011 on Plastic Materials and Articles intended to come into contact with food. Overall migration testing was performed using simulant A (Ethanol 10%) and simulant B (3% Acetic Acid) at test conditions OM6 (four hours at reflux) and simulant D2 (Olive Oil) at test conditions OM7 (two hour at 175°C). The Surface Area to Volume (S/V) ratio used was 2 dm2 to 100 ml of test simulant;
- 3) The monomer tetrafluoroethylene used in this product is subject to a specific migration limit of 0.5 mg/kg in food or food simulants;
- 4) Dual Use Additives subject to restrictions in food as defined in (EC) No. 1333/2008 and (EC) No. 1334/2008 are not used in the manufacture of this product.

Based on its composition it is unlikely that Garlock Gylon® Style 3549 Lip Seal Material will bring about an unacceptable change in the composition of the food, or a deterioration of its organoleptic characteristics. Due to the wide range foods and operating conditions however it is the responsibility of the end user to determine suitability.

Declaration of Compliance to U.S. Food and Drug Administration, Code of Federal Regulations, Title 21:

Garlock Gylon® Style 3549 Lip Seal Material may be used for repeated contact with all food types under all conditions of use as they comply with relevant FDA requirements for food contact substances. Consistent with 21 CFR 174.5(d), each component is composed of substances that are either:

- 1) Listed or affirmed as Generally Recognized As Safe (GRAS) under 21 CFR Parts 182 or 184;
- 2) Covered by, and meeting all relevant specifications and other requirements in an indirect food additive regulation under 21 CFR Parts 175, 176, 177 and 178.

In accordance to GMP the food contact article shall be thoroughly cleaned prior to first use in contact with food.

Michael P. McNally Principal Chemist

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