

GYLON[®] Brown-White Style 3549

Lip Seal Material Dossier



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GYLON® Brown-White Style 3549

For the special challenges in the food and pharmaceutical industry

Section 01

Supplier Information

Name: Garlock Sealing Technologies

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Parent Company: EnPro Industries

Section 02

Product Description

Product Name: GYLON® Brown-White Style 3549 Lip Seal Material

Description: Abrasion Resistant Lip Seal Material for Food and Pharmaceutical

Applications Color: White / Tan

Section 03

Shelf Life

The shelf life is indefinite.

Section 04

Safety Data Sheet (SDS)

SDS is available at: www.garlock.com
SDS From GST Website

Section 05

Transmissible Spongiform Encephalopathies (TSE) / Bovine Spongiform Encephalopathy (BSE)

GYLON® Brown-White Style 3549 Lip Seal Material contains no by-products of animal origin of specified risk material, or additives. No products of bovine origin are used in the manufacture of: GYLON® Brown-White Style 3549 Lip Seal Material; therefore there is no source for BSE or TSE materials or to contaminate our products.

Section 06

Restricted Substance

GYLON® Brown-White Style 3549 Lip Seal Material is not formulated with any of following substances:

Arsenic	Mercury
Asbestos	Nonyl Phenol
Antimony	Polybrominated biphenyls (PBB)
Bisphenol A	Polybrominated diphenyl ethers (PBDE)
Cadmium	Perfluorooctanoic acid (PFOA)
Formaldehyde	Perfluorooctanesulfonic acid (PFOS)
Hexavalent Chromium	Resorcinol
Lead	Silicone
Melamine	

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Section 07

REACH SVHC

Garlock Sealing Technologies has investigated the need to register this product and has determined that this product meets the definition of an article per the REACH legislation EC 1907/2006. Therefore, Garlock Sealing Technologies has no obligations for registration under the requirements of REACH.

GYLON® Brown-White Style 3549 Lip Seal Material does not contain any of the listed Substances of Very High Concern (SVHC) set forth by the European Chemicals Agency (ECHA) in decision ED/67/2008 on October 28, 2008 and updated on July 7, 2017.

REACH Compliance Statements are available on the internet at <https://www.garlock.com/en/technical-resources/downloads>. Select the Approvals and Certifications at drop down list of File Type and find the corresponding document.

Section 08

RoHS Status

GYLON® Brown-White Style 3549 Lip Seal Material conforms to European Commission Directive (2011/65/EU) and does not contain more than 0.1% by weight of lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE), and no more than 0.01% by weight of cadmium.

REACH Compliance Statements are available on the internet at <https://www.garlock.com/en/technical-resources/downloads>. Select the Approvals and Certifications at drop down list of File Type and find the corresponding document.

Section 09

Conflict Mineral Statement

Information available at: <http://www.enproindustries.com/corporate-governance/conflict-minerals-compliance>

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Section 10

Food Contact Statement

Food Contact Declaration

Garlock GYLON® Brown-White Style 3549 Lip Seal Material

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

GYLON® Brown-White 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:

- 1) (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® Brown-White 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® Brown-White 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.

Section 11

USP Statement

GYLON® Brown-White Style 3549 Lip Seal Material has met the requirements of USP <87> Biological Reactivity Tests, In Vitro; Elution Test, in accordance with USP 39-NF 34 through Second Supplement, Official December 1, 2016 to April 30, 2017.

GYLON® Brown-White Style 3549 Lip Seal Material has also met the requirements of USP <88> Biological Reactivity Tests, In Vivo in accordance with USP 40-NF 35, Official May 1, 2017 to July 31, 2017 for Class VI designation at a temperature extraction of 121°C for 1 hour.

Document No: 0302

Effective Date: 11/1/2017

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Note:
Properties/applications shown throughout this brochure are typical. Your specific application should not be undertaken without independent study and evaluation for suitability. For specific application recommendations consult Garlock. Failure to select the proper sealing products could result in property damage and/or serious personal injury. Performance data published in this brochure has been developed from field testing, customer field reports and/or in-house testing. While the utmost care has been used in compiling this brochure, we assume no responsibility for errors. Specifications subject to change without notice. This edition cancels all previous issues. Subject to change without notice GARLOCK is a registered trademark for packings, seals, gaskets, and other products of Garlock.
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