

NEWMAN™

SANITARY GASKET COMPANY

Newman 2107LE EPDM Gaskets **A New Standard for the Biopharmaceutical Industry**



Compatible with CIP, SIP, WFI and Processing areas. Higher Purity, Longer Life, Easier Maintenance¹

Lower Extractables

- 10X less than conventional formulations

Longer Service Life

- Little to no wear after 500 pure steam exposure cycles (ASME BPE Appendix K)

Better dimensional stability

- Little to no intrusion into the process stream

Easier Maintenance

- 2107LE EPDM gaskets disassemble after long periods of exposure with little effort (static friction) and no residue on fittings
- 2107LE supports the weight of equipment better and holds tubing in alignment better than other compounds, all without cracking or tearing

All Biopharmaceutical Certifications and More:

- FDA (21CFR177.2600)
- USP Biocompatibility (USP <87>, USP <88> Class VI)
- Free of ADI, Latex, REACH, RoHS (I and II), ICHQ3 Solvents, etc.

Designed for Biopharmaceutical Applications

For 40 years Newman has set the standard for the Biopharmaceutical Industry in supplying high purity, high performance gaskets. Newman realizes that gaskets must not only meet key industry requirements, but also provide the biopharmaceutical engineer with what is needed to protect the process, the product and the patient. Newman 2107 EPDM has always risen to the challenge and 2107LE EPDM follows that legacy.

Worldwide Certifications

Fully synthetic, 2107LE complies with a multitude of international regulations, standards and customer requirements (i.e. FDA, USP, EU, EP, REACH, RoHS I and II, ICH Q3D Residual Solvents and Elemental Impurities, Free of ADI, Latex, BPA, Phthalates, etc.). 2107LE also meets global requirements for biopharmaceutical processing.

[1] The information contained herein is offered in good faith and is believed to be accurate at the time of writing. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that our products are safe, effective, and fully satisfactory for the intended end use. **NEWMAN SANITARY GASKET CO. (NSG) SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY. NSG DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.**

For more information, contact us at:

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NEWMAN 2017LE EPDM GASKETS

Performance Designed and Tested:

Figure 1 shows a comparison of test results between 2017 and 2017LE. Although 2107LE will find broad application in other high purity processing industries, this proprietary Newman compound was developed and tested over the course of five years *specifically for the Biopharmaceutical Industry*. This included not just physical property testing, but also chemical exposure to specific solvents used in the industry and longevity performance testing on Newman's in-house testing facility which mimics biopharmaceutical processes. 2107LE has surpassed all materials ever tested in terms of:

Long term

- Dimensional stability
- Sealing characteristics
- Resistance to purified steam
- Maintenance of a flush connection between connecting ferrules per ASME BPE Intrusion requirements.ⁱ



After 500 steam cycles¹, 2107LE gaskets show easy removal, little intrusion, no wear and clean mating surfaces

Figure 1: Traditional 2017 vs 2107LE (Typical Properties)

Property	2107	2107LE
Shore A Durometer, points	73	77
Tensile Strength, psi (MPa)	1500 (10.3)	2900 (20)
Ultimate Elongation %	260	180
100% Modulus, psi (MPa)	330 (2.3)	800 (5.5)
Compression Set, % 22 hrs@212°F (100°C, typical)	12	8
Max Operating Temperature, °F (°C)	275 (135)	325 (163) ⁱⁱⁱ
Min Operating Temperature, °F (°C)	-55 (-48)	-58 (-50) ⁱⁱⁱ
Compliance	See attached	See attached

2107LE has better tensile strength and modulus:

- Key requirements when it comes to piping alignment and equipment support. This translates into less overall compression of the joint, maintaining a flush connection for good cleaning and draining independent of seal loading.

2107LE also has better compression set:ⁱⁱ

- Required for a more consistent seal between the gasket and mating surfaces of the ferrules during the course of use.

2107LE also has an outstanding operating temperature range:

- Tg of -50°C and upper limit above 325°C ⁱⁱⁱ means more latitude in processing than ever before.

2107LE also uses Newman's proprietary gasket design:

- This prevents crevices or excessive intrusion both when gaskets are under-tightened and over-tightened. There is less risk of entrapped materials around and between the components of the piping connection. *Form and fit are unchanged.*

ⁱ ASME Bioprocessing Equipment Standard, Part SG-4.2 (2106 ed.)

ⁱⁱ According to ASTM D395 Method B, 25% compression during testing.

ⁱⁱⁱ Intermittent exposure to higher temperatures is acceptable. Gasket longevity is reduced accordingly. Tg (Glass Transition Temperature) determined by DSC. TGA (Thermogravimetric Analysis) shows less than 0.5% loss in material to 237°C (460°F). This means intermittent exposure to 400°F should be acceptable. 325°F chosen as a safe upper limit.

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Lower Extractables:

Figure 2 illustrates that while Newman's Industry leading 2107 has very good extractable profiles, 2107LE takes that one step further. Containing only 10% of the total hexane extractables of our previous 2107, lower extractables means *higher purity drug products*.



Figure 2 - FDA Extraction ^{iv}

SAMPLE ID	EXTRACTION TIMES	SOLVENT	EXTRACTABLE CONTENT mg/in.2	REQUIREMENT mg/in.2 max.	PASS/FAIL
2107	First 7 hrs.	Distilled Water	0.2	20	PASS
2107	Next 2 hrs.	Distilled Water	None Detected	1	PASS
2107	First 7 hrs.	Hexane	74.5	175	PASS
2107	Next 2 hrs.	Hexane	1.0	4	PASS
2107LE	First 7 hrs.	Distilled Water	0.1	20	PASS
2107LE	Next 2 hrs.	Distilled Water	0.3	1	PASS
2107LE	First 7 hrs.	Hexane	7.7	175	PASS
2107LE	Next 2 hrs.	Hexane	1.5	4	PASS

^{iv} Data generated by third party (Akron Rubber Development Laboratories).

NEWMAN 2107LE EPDM GASKETS

Better Fluid Resistance:

Figure 3 shows how 2107LE responds to common solutions used in the Biopharm industry. While Newman 2107 is excellent, Newman 2107LE is even better. [▼] Less swelling and weight gain means less absorption and desorption of process materials. Once again, 2107LE takes your drugs to a new level of purity.



Figure 3 – Fluid Immersion Properties

SAMPLE ID	TEMPERATURE. °C	SOLVENT	WEIGHT CHANGE. %	VOLUME CHANGE. %	DUROMETER CHANGE, POINT CHANGE
2107	70	0.5M Sodium Hydroxide	+2.9	+5.6	-10
		0.12M Phosphoric Acid	+2.7	+2.1	-1
		Polysorbate 50 0.5% V/V	+2.6	+2.0	-1
		Citric Acid 10%	+2.7	+2.2	-2
2107LE	70	0.5M Sodium Hydroxide	+1.3	+1.6	-1
		0.12M Phosphoric Acid	+1.3	+1.5	-1
		Polysorbate 50 0.5% V/V	+2.1	+2.5	-3
		Citric Acid 10%	+1.3	+1.5	-2
2107	25	Benzyl Alcohol 2%	+0.8	+0.7	+6
		Sodium Hypochlorite 400mM	+0.5	+0.2	+1
		Acetic Acid >50mM	+1.2	+1.1	+1
		Sodium Citrate 25mM@4.1pH	+0.5	+0.4	+6
		Sodium Citrate 0.57M @6.0pH	+0.4	+0.4	+6
2107LE	25	Benzyl Alcohol 2%	+0.4	+0.5	+7
		Sodium Hypochlorite 400mM	+0.1	+0.2	-1
		Acetic Acid >50mM	+1.6	+1.9	0
		Sodium Citrate 25mM @4.1pH	+0.1	+0.2	-6
		Sodium Citrate 0.57M @6.0pH	+0.1	+0.2	-6

[▼] Data generated by third party (Akron Rubber Development Laboratories).

2107LE - A New Standard of Purity and Performance:

2107LE sets a new standard for EPDM gaskets used in CIP, SIP WFI and processing areas of the Biopharmaceutical Industry
 2107LE: *The new standard of purity and performance.*

- Lower Extractables – 10X Lower
- Longer Service Life – Little to no wear after a simulated year of service
- Better Dimensional Stability – Better cleaning and draining, better equipment support
- Easier Maintenance – easy disassembly after use, better process piping alignment
- All Biopharmaceutical Certifications and more – FDA, USP, REACH, RoHS, ICHQ3 and more

Request your samples today!

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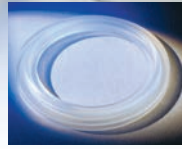
NEWMAN SANITARY GASKET LINE CARD



Newman superior products give you maximum performance and unequaled longevity for product life. Certified FDA & 3-A compliant compounds — Buna, EPDM, Viton™, Silicone, and Teflon™

LIM Gaskets

(Liquid Injection Molding) Provide precision silicone gaskets for the food, pharmaceutical and biotech industries.

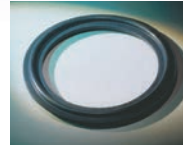
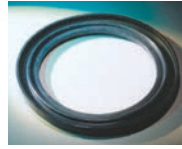
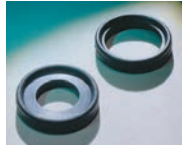


PTFE Encapsulated EPDM

Clamp style EPDM chemically bonded to a thin layer of PTFE. Improved resistant to cold flow, creep; increased flexibility and sealing performance.

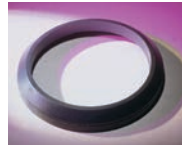
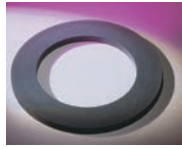
Class VI Material

EPDM, Viton™, Teflon™ and Silicone compounds have been tested and certified to be in compliance with the USP Class VI Criteria.



Clamp Gaskets

- Standard
- Flanged
- Teflon™ Envelope
- Encapsulated Gasket



Bevel Seat Gaskets

- Standard 45° C.I.P., 90 durometer
- Teflon™ - standard & heavy duty
- Flat style

"O"-Rings

For popular centrifugal and positive displacement pumps and equipment. All standard sizes available. The largest inventory of FDA compliant "O"-Rings in North America.



Q&I Line Gaskets

- Available in all compounds

Pipe Hanger Sleeve System

For processing piping applications; outperforms conventional assembly systems in every way.



Schedule 5 Gaskets

- Standard
- Teflon™ Envelopes
- Flanged
- I-Line

Silverback™

50/50 blend of PTFE and 316 stainless steel. Longer service life than traditional PTFE.



Orifice Plates

- 316L stainless steel inserts
- Bonded or removable
- Solid rubber EPDM, Buna, & Viton™
- Solid Teflon™ (no stainless steel insert)

Sock Screen Gaskets

For plant intake and bulk tank applications. Speeds unloading and reduces cost.



Screen Gaskets

- Available in 316 wire mesh and perforated disc in a number of sizes.
- Bonded or removable

Gauge Guard Isolator Gaskets

Protect your gauges from your process. Offered in EPDM and Platinum Cured Silicone.



Casing Gaskets

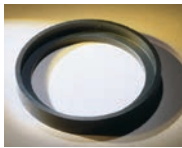
For centrifugal pumps.



Body Gaskets

- For automatic air valves.
- 316 stainless steel insert
- Solid rubber

John Perry
Buna, EPDM, Viton™, Silicone, and Teflon™



Acrylic Sight Glass

Available in four styles:
• Tri-Clamp • I-line
• Q-Line • Bevel Seat



Tank Gaskets

- For all tanks, single and double flanged styles.
- Sight glass gaskets.

ISO2852/DIN32676 Gaskets

Hygienic flanged clamp gaskets for the food, pharmaceutical and biotech industries. Manufactured in Viton™, EPDM, Teflon™, Teflon™ Envelope and Silicone that meet both FDA and Class VI criteria.



Custom Molded Parts

Products made to your specifications out of a wide range of materials.

PRODUCTS OF INTEGRITY...FROM PEOPLE OF INTEGRITY