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Change Notification#: PCN 3207-3227-22-01

Change Title: Viton[™] A Discontinuation for FDA/USP Applications

All FDA/USP Parts Using Chemours Viton™ Ai

All Part Numbers

Date of Publication: August 20, 2022

Product Change Notification

Notification Summary:

Newman Sanitary Gasket Co. was informed that The Chemours Company will discontinue supply of Genuine VitonTM A products to FDA and USP manufacturers on January 1, 2023. This will affect all Newman articles (Orings, gaskets, extrusions and custom parts) made from both Newman 3207 Black VitonTM A and Newman 3227 White VitonTM A. In response, Newman is developing a new grade of Genuine VitonTM GBL *as the replacement* for VitonTM A to fill the need in the affected industries requiring a similar lower temperature limit. Newman Sanitary Gasket Company currently offers O-rings, gaskets, extrusions and custom parts made from Chemours peroxidecured Genuine VitonTM GF and ETP grades which offer better chemical resistance.

Figure 1: VitonTM A Compounds vs VitonTM GF, GBL and ETP Compoundsⁱⁱⁱ

Newman Compound No. Typical Properties	3207/3227	3197GBL/ 3127GBL	3197GF	3107ETP
Viton™ Base Resins	Viton™ A	Viton [™] GBL	Viton GF	Viton ETP
Color	Black/White	Black/White	Black	Black
Shore A Durometer, points	78	73	73	73
Tensile Strength, psi (MPa)	1700 (11.7)	2300 (15.8) Black /1500 (10.3) White	2300 (15.8)	1700 (11.72)
Ultimate Elongation % (min)	225	350/350	350	260
100% Modulus, psi (MPa)	950 (6.6)	500 (3.45)	500 (3.45)	500 (3.45)
Compression Set, % 70 hrs@392°F (200°C)	10(3207)/ 20(3227)	10(Black)/ 20(White)	15	30
Operating Temperature, °F	-2(-18) to	-2(-18) to	18(-8) to 450	10(-12) to
(°C)	450(232)	450(232)	(232)	450 (232)
Compliance	FDA/USP/3A/etc	FDA/USP/3A/etc	FDA/USP/3A/etc	FDA/USP
Intended Application	Discontinued	FDA	USP	FDA/USP
Relative Price	\$	\$	\$\$	\$\$\$\$
Planned Newman Stock Availability	No Longer Available	Wide - Replaces Viton™ A	Limited	Made to Order

Parts using Newman 3207 and 3227 compounds may be identified by compound identifiers on Newman Certifications (see below) and by part number.

Customer Name:
P.O. Number:
Item:
NSGCO Part Number:
Customer Part Number:
Quantity:
Batch Number:
Compound:
Cure Date:
Date Signed:

Figure 2: Compound Identifier on Newman Standard Certs

Compound Specifications are available from Newman Sanitary Gasket Co.

Availability of these compounds, their related parts and their substitutes is limited, and supply disruptions are anticipated through the end of 2022. Orders for components using 3207 and 3227 will be subject to availability. Delivery dates cannot be guaranteed.

Samples of equivalent parts made from alternative compounds will be shipped based on availability.

Key Characteristics of this Change:

- Material Discontinuation: Chemours has elected to no longer supply the base resins (Viton[™] A) for FDA and USP applications.
- Alternative Materials: Alternative Newman compounds (made from Viton[™] GF and Viton[™] ETP) already exist and are being provided based on availability. Additional compounds are also being developed (Viton[®] GBL). Typical properties are as described in Figure 1. Specifications are available upon request.
- Compliance/Certification Change: Compliances are shown in Table 1. Some testing of alternatives is still in progress.
- Part number changes: For part numbers of substitute materials, please contact Newman Sanitary Gasket Company. Not all part numbers exist as of this date.

Forecasted Key Milestones (Anticipated):

Customer Notification: Effective Immediately.

• Substitute Sample Availability: Part numbers using current compounds may be ordered

immediately. Part numbers with new compounds are expected third

quarter 2022.

New Part Sales: Supply disruptions expected in 2022.

Last 3207 and 3227 Orders
 Subject to availability.

Description of Change to the Customer:

See Notification Summary.

Affected Parts:

All FDA and USP gaskets, O-rings and Customs made with Newman Compounds 3207 or 3227.

Identification of Affected Parts:

- All parts using Newman 3207 or 3227 Viton[™] A compounds.
- Contact Newman Customer Service for questions.

<u>Customer Impact of Change and Recommended Action:</u>

- This is a material discontinuation/change and as such is considered a major change. Although new
 materials are considered a "like for like" change (or better), a qualification review is suggested for critical
 applications. Safety retesting may be required for hazardous applications.
- Chemical Resistance/Compatibility of suggested alternatives is considered better. VitonTM GBL Chemical Resistance (although not documented by Chemours to the extent of Viton A and GF) is midway between the VitonTM A and GF. (https://www.newmangasket.com/assets/files/GF and ETP Comparison18.pdf).
- Most custom parts will not need new tooling. Contact Newman for ordering customs in the desired material. Not all standard gaskets and O-rings are yet available in the new materials. A review of size requirements should be performed.
- Hardness differences and slight dimensional changes between the materials may change torque requirements during assembly, especially where a flush connection is required (e.g. Biopharma Applications).
- 3A applications should be reviewed. Check listings at https://www.3-a.org/.
- Newman recommends notification of end users.
- Determine if key components of your processing systems need verification or extra inspection until a history of service is accumulated.

Reference Documents/Attachments:

- Viton® Chemical Resistance Comparisons:
 https://www.newmangasket.com/assets/files/GF and ETP Comparison18.pdf
- Current Status of this PCN may be viewed online at www.newmangasket.com/news.

Feel free to contact Newman Sanitary Gasket below for any further questions or concerns.

Sincerely,

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Newman Sanitary Gasket Company Change Notification

i Viton™ is a registered trademark of the Chemours Company.

ii GBL values are based on current limited data.

iii Tabulated values should not be taken as specifications, but as typical results. Value is listed once when both White and Black Compound have similar values. Contact Newman for specifications of individual compounds.