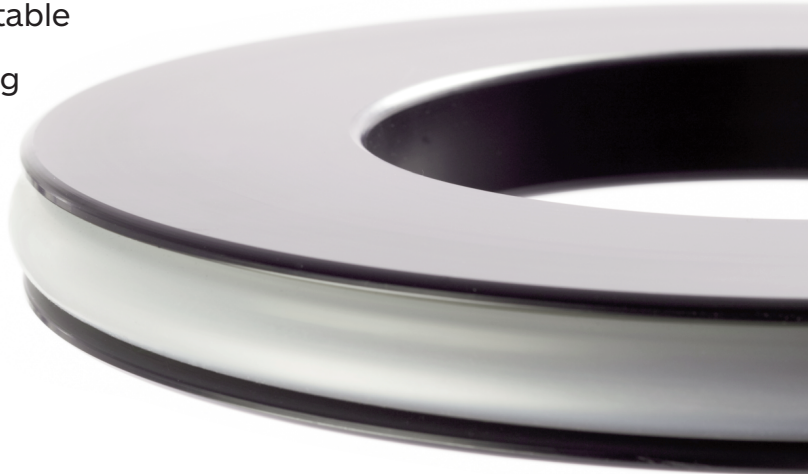


A new line of inflatable seal compounds that meet U.S. Pharmacopoeia (USP) Class VI certification is now available from Pawling Engineered Products. The CVI™ Series meets the specific needs of pharmaceutical equipment manufacturers who seek the assurance of USP Class VI compound certification for their inflatable seals. The compounds are available in silicone and EPDM.

The CVI Series combines use of the right materials for biocompatibility with the unique characteristics needed for inflatable seals, including temperature and/or chemical resistance. These compounds address a growing trend among pharmaceutical equipment manufacturers towards use of materials that are certified to USP Class VI, the most stringent protocol for classification of compounds used in most medical and other healthcare applications. Among many advantages certification offers is an added level of confidence that assures favorable compatibility results, reducing the burden of regulatory compliance.



Applications and Specifications

The CVI Series is especially designed for inflatable seals used in a wide range of pharmaceutical and medical seal applications. The compounds are readily available in the Type 1 PRS573 profile and all Type 10X designs, or can be customized to suit any unique inflatable or compression sealing application. Typical applications include:

- Inflatable sliding door seals for freeze dryers
- Hatch cover inflatable seals for CIP (clean-in-place) washers
- Inflatable seals used in variable lid chromatography columns
- Fluid bed dryer inflatable seals
- Inflatable sterilizer seals

Benefits and Advantages

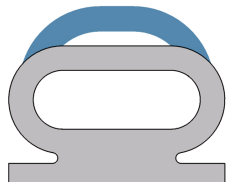
- USP Class VI certification ensures materials and processing integrity; simplifies compliance
- Outstanding combination of USP Class VI certification and world-class engineering, materials and technical expertise of industry leader Pawling Engineered Products
- Fully traceable material lots manufactured under our ISO9001-2008 certified quality system. Certificates of conformity readily available
- Good cycle life characteristics
- Good physical properties



CVI Series Technical Data

USP Class VI Profile Availability

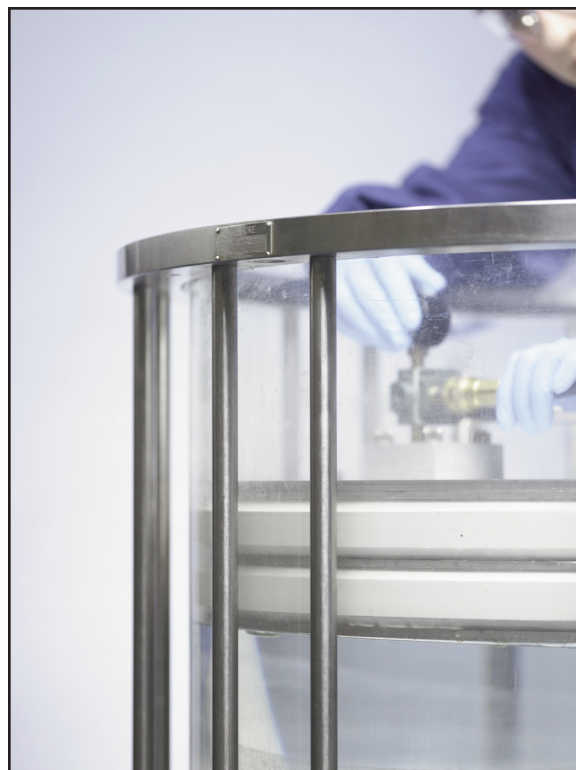
Type 1



Type 10X



| Profile | Type | Width in [mm] | Height in [mm] | Design Gap in [mm] |
|---------|------|---------------|----------------|--------------------|
| PRS573 | 1 | .687 [17.45] | .437 [11.10] | .125 [3.18] |
| PRS991 | 10X | .256 [6.5] | .197 [5] | .059 [1.5] |
| PRS993 | 10X | .551 [14] | .394 [10] | .118 [3] |
| PRS995 | 10X | .630 [16] | .472 [12] | .118 [3] |
| PRS997 | 10X | .827 [21] | .945 [24] | .197 [5] |
| PRS999 | 10X | 1.378 [35] | 1.260 [32] | .394 [10] |



Material Characteristics

EPDM (E552)

- Good permeability
- Compatible with polar solvents, such as Acetone and Ethyl Acetate
- Resistant to acid attack

Silicone (S60121)

- Industry proven biocompatibility
- Clean, low bleed
- Excellent temperature resistance

Physical Properties

| Material | Silicone | EPDM |
|----------------------------------|---------------|-------------|
| Compound ID | S60121 | E552 |
| Color | Translucent | Black |
| Specific Gravity | 1.16 | 1.02 |
| Durometer (Shore A) | 62 | 52 |
| Tensile Strength (psi) | 1300 | 1500 |
| Elongation (%) | 600 | 450 |
| Tear Strength, Die C | 275 | 105 |
| Compression Set (22 hrs @ 125°C) | | 21% |
| Compression Set (22 hrs @ 175°C) | 29% | |

Note: these results are typical for our CVI inflatable silicone and EPDM compounds.

The U.S. Pharmacopoeia (USP) is a scientific, non-profit organization that sets quality standards for food ingredients, dietary supplements, pharmaceuticals and their associated supply chains. Testing and certification were provided by Toxicon Corp., Bedford, Mass.

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