AdvantaFlex®



BIOPHARMACEUTICAL APPLICATIONS
PRODUCT DATASHEET



SEALABLE & WELDABLE TPE TUBING

AdvantaFlex is a translucent TPE (Thermoplastic Elastomer) single-use tubing specifically designed for fluid transfer in critical pharmaceutical and biopharmaceutical applications, where reliability, safety, and sustainability are top priorities. With its sealable and weldable properties, AdvantaFlex tubing is the material of choice in various configurations, including over-molding applications, ensuring optimal fluid management integrity. Even after sterilization, AdvantaFlex maintains its physical properties and translucency while resisting kinking, making it an ideal choice for quality and performance.



KEY FEATURES & BENEFITS

- · Translucent for fluid flow visibility
- High-quality aseptic sealing disconnection
- · High strength, quality aseptic welded connections
- · Low adsorption and good chemical resistance
- Available as leak-proof simple or complex overmolded connections and tubing
- Operating temperature range -40°C to +60°C (-40°F to +140°F)

- · Certified free of silicone oils
- · Custom lengths, sizes, and packaging available
- · Security of supply with redundant manufacturing sites
- · Manufactured with a focus on sustainability
- Comprehensive <u>Validation Package</u> to expedite qualification and validation, including full extractables report (BPOG)

TYPICAL APPLICATIONS



Aseptic welding connections



Aseptic sealing disconnection



Single-use fluid transfer sets



Pharmaceutical production, sampling and delivery systems



Cell media, harvesting, and fermentation.



Ideal for use in assemblies, molded, and bags manifolds



Filtration

PHYSICAL PROPERTIES

	ASTM Method	Value
Durometer, Shore A	D2240	65
Specific Gravity	D792	0.89
Ultimate Tensile, psi (MPa)	D412	1000 (6.89)
Ultimate Elongation, %	D412	550
Tensile Modulus @100%, psi (MPa)	D412	410 (2.83)
Tensile Modulus @300%, psi (MPa)	D412	640 (4.41)
Tear Strength, Die B, ppi (kN/M)	D624	240 (42.0)
Compression Set, %	D395B	25

CHEMICAL COMPATIBILITY

Acids, Dilute / Weak	Acceptable
Acids, Strong / Concentrated	Acceptable
Bases, Dilute / Weak	Acceptable
Bases, Strong / Concentrated	Acceptable
Salts	Acceptable
High Purity Water	Acceptable
Oil / Water Emulsion	Test Before Using
Alcohol*	Not Recommended
Organic Solvent	Not Recommended

^{*} Brief or intermittent contact is acceptable

COMPLIANT OR TESTED TO

BPOG Extractables/Leachables

USP <87> Cytotoxicity MEM Elution

USP <88> Class VI

USP <85> Bacterial Endotoxin

European Pharmacopeia 3.2.9

ISO 10993-5 (Cytotoxicity, In Vitro)

RoHS Compliant

REACH Compliant

ADCF Compliant

Review the Regulatory Overview chart

STERILITY

Available with validated sterility assurance of 10⁻⁶ via gamma irradiation per ISO 11137 method VDmax 25. A full product validation guide data is available upon request.

STERILIZATION METHODS

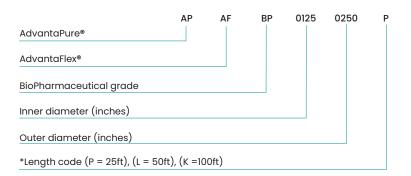
Autoclave	One-time cycle at 121°C, 30 min.				
Gamma Irradiation	One-time up to 40 kGy				

DS-APAF-R[2]

PRODUCT SPECIFICATIONS

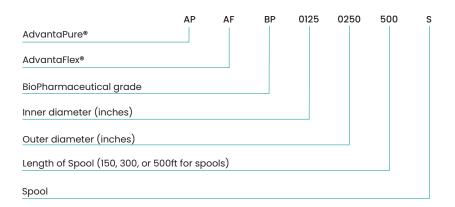
Part No.	Catalog No.	I.D.		W	Wall		O.D.		Working Pressure 70°F (21.1°C)		Standard Lengths	
		in	mm	in	mm	in	mm	PSI	Bar	ft	m	
A7500077	APAF-BP-0125-0250	0.125	3.18	0.062	1.57	0.250	6.35	30	2.1	50, 100, 500*	15.24, 30.48, 152.40	
A7500155	APAF-BP-0188-0313	0.188	4.76	0.062	1.57	0.313	7.94	23	1.6	50, 100	15.24, 30.48	
A7500207	APAF-BP-0188-0375	0.188	4.76	0.094	2.38	0.375	9.52	32	2.2	50, 100	15.24, 30.48	
A7500285	APAF-BP-0250-0375	0.250	6.35	0.063	1.59	0.375	9.52	20	1.4	50, 100	15.24, 30.48	
A7500311	APAF-BP-0250-0438	0.250	6.35	0.094	2.38	0.438	11.11	23	1.6	50, 100, 300*	15.24, 30.48, 91.44	
A7500337	APAF-BP-0250-0500	0.250	6.35	0.125	3.18	0.500	12.70	30	2.1	50	15.24	
A7500415	APAF-BP-0313-0500	0.313	7.94	0.094	2.38	0.500	12.70	24	1.6	50	15.24	
A7500480	APAF-BP-0375-0500	0.375	9.52	0.062	1.57	0.500	12.70	18	1.3	100	30.48	
A7500493	APAF-BP-0375-0563	0.375	9.52	0.094	2.39	0.563	14.30	23	1.6	50	15.24	
A7500506	APAF-BP-0375-0625	0.375	9.52	0.125	3.18	0.625	15.88	24	1.6	50, 100, 150*	15.24, 30.48, 45.72	
A7500584	APAF-BP-0500-0750	0.500	12.70	0.125	3.18	0.750	19.09	22	1.5	50, 100*	15.24, 30.48	
A7500662	APAF-BP-0625-0875	0.625	15.88	0.125	3.18	0.875	22.23	18	1.3	50	15.24	
A7500753	APAF-BP-0750-1000	0.750	19.05	0.125	3.18	1.000	25.40	17	1.2	50, 75*, 100	15.24, 22.86, 30.48	
A7500766	APAF-BP-0750-1125	0.750	19.05	0.188	4.76	1.125	28.58	18	1.3	100	30.48	
A7500857	APAF-BP-1000-1375	1.000	25.40	0.188	4.76	1.375	34.93	18	1.3	25	7.62	

Sold by standard length only. Add length suffix code to product number when ordering. Example: 25 ft. of 0.125 in. I.D. x 0.250 in. O.D. tubing is catalog number APAF-BP-0125-0250P.





*Example: 500 ft. spool of .125 in. l.D. x .250 in. O.D. tubing is catalog number APAF-BP-0125-0250-500S.



Non-listed sizes and custom lengths are available by special order.

Working pressures are calculated from burst testing using a 3:1 safety factor. Application testing is recommended.

Coils and spools are supplied double-bagged in heat-sealed polybags and bulk packed. Contact your AdvantaPure Sales Representative for other packaging options. Working pressures are calculated from burst testing using a 3:1 safety factor.

NOTE: The data listed throughout this datasheet is meant only as a guide to aid in the design and is believed to be reliable; however, nothing stated shall constitute a guarantee or warranty for any application. Product field testing should be performed to find the actual values for a specific application.

DS-APAF-R[2]

ADVANTAFLEX® TPE INTEGRATION OPTIONS

Overmolded Connections: Wyes, tees, sanitary ends, intersections, and reducers.

Molded Assemblies: All AdvantaFlex sizes can be integrated into our AdvantaPure assemblies and manifolds, eliminating mechanical connections, and providing a smooth, leak-free inner surface.

Sealed Tubing Ends: Weld to bags or container closures for sampling and storage applications. Ideal for reducing operational costs, improving production efficiencies, and reducing cross-contamination.

Molded Tubing Ends: Ideal for aseptic transfer and processing, over-molded with multi-tube TC's and sanitary ends to form a smooth fluid path.

Bioreactor Tubing Kits: Built-to-order in an ISO Class 7 clean room, assembled with various components for convenience and efficiency.

Sterile Bottle Assemblies: Provide a ready-to-use, cost-effective solution for aseptic sampling, cell growth, and filling application. The robust molded closure design features a continuous flow path.



WARRANTY: NewAge Industries AdvantaPure products are warranted to be free from defects in material and workmanship. Any product found to carry such defects will be replaced without charge. This warranty is limited only to the replacement of NewAge Industries AdvantaPure products, item for item, which after examination by NewAge Industries AdvantaPure are deemed defective. NewAge Industries AdvantaPure specifically disclaims any other liability. The data supplied is provided as a helpful guideline and is believed to be reliable; however, nothing stated shall constitute a guarantee, recommendation, or warranty for any application.

NOTICE: NewAge Industries, Inc. has been a privately owned corporation since 1954. Neither the corporation nor its principals are affiliated, in any way, with any other group or entity either representing themselves as or being referred to by the term NewAge.

© Copyright 2023. All Rights Reserved





145 James Way • Southampton, Pennsylvania 18966 USA **888-506-3924 • 215-526-2300**

AdvantaPure®. AdvantaFlex®, NewAge®, and "Fluid Transfer Specialists®" are registered trademarks of NewAge® Industries, Inc.

Reproducing this document or any part thereof, in any form whatsoever, is prohibited without express written permission of NewAge® Industries, Inc.

www.pharmasep.fr contact@pharmasep.fr +33 (0)4 74 71 94 71