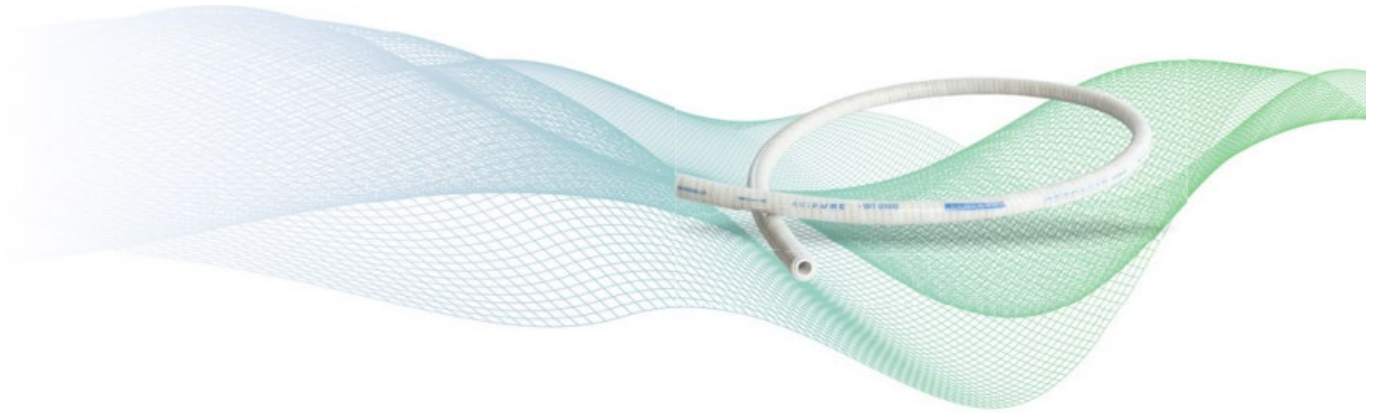
IDEEN FÜR IHREN ERFOLG.

LÖSUNGEN FÜR DIE PROZESS-
UND LIFE SCIENCE INDUSTRIE

AVIPURE® – WT Certification Package



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Content

1 Introduction

1.1 Development and Production of AVIPURE®-WT

avintos AG specified the technical requirements for their AVIPURE®-WT (Wire-reinforced silicone hose with Chemours (Dupont) Teflon PTFE 62 inliner) and has them manufactured through their partner TUBIGOMMA DEREGIBUS S.r.l., 35030 Saccolongo PD, Italy.
AVIPURE® is a registered Trademark of avintos AG.

1.2 About TUBIGOMMA DEREGIBUS (TUDERTECHNICA)

TUDERTECHNICA is a privately-owned Company founded in 1983 that offers to the clients a modern, efficient manufacturing facility and a qualified and experienced staff, for the purpose of creating original customized products that meet the requests from the international market.
TUDERTECHNICA designs and manufactures specialty technical hoses for a wide range of applications in the food, chemical, petrochemical, pharmaceutical, cosmetic and for other industries requiring high performance hoses. They operate in a modern and efficient manufacturing plant employing the rigid mandrel production process.

1.3 Certified production

AVIPURE®-WT (Wire-reinforced silicone hose with Chemours (Dupont) Teflon PTFE 62 inliner) are manufactured, tested, and packed with an approved manufacturing process.
Consistent high quality of Chemours (Dupont) Teflon PTFE 62 inliner hose is assured by careful selection of the raw material, well planned and validated production technologies, and an efficient Quality Assurance Department, all of which result in high batch-to-batch reproducibility.

1.4 Quality Management System

TUDERTECHNICA is certified according to ISO 9001:2015 and ISO 45001:2018.
avintos is certified according to ISO 9001:2015.
You may download the certificates from the respective websites.

2 Technical Specifications

2.1 Hose Dimensions, Type and Part Numbers Overview

AVIPURE®-WT (Wire-reinforced silicone hose with Chemours (Dupont) Teflon PTFE 62 inliner) are covered with silicone and are manufactured in several dimensions.
The color of the PTFE inliner is white while the silicone cover is natural without addition of color pigments.
All hose coils are provided in a simple PE bag packaged in a cardboard box.

Further dimensions upon request.

TYPE	ID x OD DIMENSIONS	VACUUM	WORKING PRESSURE AT 20°C	MINIMUM BURST PRESSURE AT 20°C	MINIMUM BEND RADIUS	HOSE COIL LENGTH	WEIGHT	ARTICLE-NUMBER
AVIPURE®	MM	BAR	BAR	BAR	MM	M	KG/M	
WT 500	13 x 24	0.9	10	40	60	10	0.4	407HSWT0500-10
WT 750	19 x 30	0.9	10	40	90	10	0.7	407HSWT0750-10
WT 1000	25 x 36	0.9	10	40	115	10	0.8	407HSWT1000-10
WT 1250	32 x 43	0.9	8	32	150	10	1.1	407HSWT1250-10
WT 1500	38 x 50	0.9	7	28	180	10	1.4	407HSWT1500-10
WT 2000	50 x 62	0.9	7	28	230	10	1.8	407HSWT2000-10

TYPE	ID x OD DIMENSIONS	VACUUM	WORKING PRESSURE AT 68°F	MINIMUM BURST PRESSURE AT 68°F	MINIMUM BEND RADIUS	HOSE COIL LENGTH	WEIGHT	ARTICLE-NUMBER
AVIPURE®	INCH	PSI	PSI	PSI	INCH	FT	LBS/FT	
WT 500	0.5 x 0.94	13	150	580	2.36	32.8	0.28	407HSWT0500-10
WT 750	0.75 x 1.18	13	150	580	3.54	32.8	0.46	407HSWT0750-10
WT 1000	1.0 x 1.42	13	150	580	4.54	32.8	0.54	407HSWT1000-10
WT 1250	1.25 x 1.69	13	115	460	5.91	32.8	0.74	407HSWT1250-10
WT 1500	1.5 x 1.97	13	105	410	7.09	32.8	0.94	407HSWT1500-10
WT 2000	1.97 x 2.44	13	105	410	9.06	32.8	1.21	407HSWT2000-10

2.2 Material Information

2.2.1 Silicone cover

AVIPURE®-WT PTFE pharma hose is made of a silicone peroxide cover material. The silicone cover is not in contact with the liquid.

Cover is a smooth silicone, translucent and heat-, ageing-, ozone- and abrasion-resistant.

2.2.2 Inliner

AVIPURE® WT inliner is made from Chemours (Dupont) Teflon PTFE 62.

The material can be used continuously in a temperature range from -40 °C (-40 °F) to +150 °C (+302 °F) without losing its integrity or deterioration of its chemical | physiological properties.
The operating temperature of the hose is directly dependent upon the specific fluid been conveyed and the length of time the fluid is in contact with the hose.

Reinforcement is made of high temperature resistant textiles and shiny stainless-steel wire helix.

2.3 Material Compliance

The Chemours (Dupont) Teflon PTFE 62 inliner of the hose is compliant to:

- EU 10_2011 and FDA CFR 21 177.1550
  Accredia Test Report 19-FC02692 June 19th, 2020
- 1907/2006/CE (REACH)
  Accredia Test Report 21LA04647 March 8th, 2021 FTALATI REACH;
- USP class VI main requirements;
  Biochem Test Report 1527-05_15 March 10th, 2016
- ISO 10993 – 5:2009, 11:2006;
  Biochem Test Report 1527-05_15 March 10th, 2016
- 3A SANITARY STANDARDS 20-27
  Cerisie Test Report 100bis/2014 May 15th, 2014

Furthermore, the Chemours (Dupont) Teflon PTFE 62 inliner has been tested and is:

- TSE/BSE free
- Asbestos free
- Phthalates free
  Accredia Test Report 21LA04647 March 8th, 2021

This statement is valid until revoked or until new information is provided.
If you require further information, please contact your responsible sales contact.

2.4 Physical Properties

AVIPURE® - WT has an inliner made of Teflon® PTFE (Chemours (Dupont) Teflon PTFE 62) which ensures a highly chemical resistance. The cover design made of silicone with braid and stainless-steel wire reinforcement gives a high-pressure resistance and maintain an outstanding flexibility.

Typical Property Data for Chemours (Dupont) Teflon PTFE 62 Fluoropolymer Resin

PROPERTY	ASTM Test Method	Value & Unit
Bulk Density		465 g/L
Average Particle Size		490 µm
Standard Specific Gravity		2.15
Rheometer Pressure*		26.9 MPa (3'900 psi)
Melting, Peak Temperature		
○ **Initial**		342 °C (648 °F)
○ **Second**		327 °C (621 °F)

*Reduction Ratio 400:1

Physical Properties silicone (hose construction)

PROPERTY	NORM	Silicone (hose construction)
Shore hardness A	ISO 48-4	60 ± 5
Specific Gravity (g/cm³)	ISO 1183	1.16
Tear strength (N/mm2)	ISO 527	35
Elongation at break (%)	ISO 527	400
Tensile strength (N/mm2)		9

2.5 Physico-Chemical Properties

2.5.1 European Pharmacopoeia: 3.1.9 & FDA regulation 21CFR, § 177.1550.

Test results
The Chemours (Dupont) Teflon PTFE 62 compound meets the requirements of the European Pharmacopoeia 3.1.9. and regulation 21 CFR, § 177.1550. The test methods, limits and results are those described in separate Report No: 19-FC02692.

2.6 Biocompatibility

Samples of the PTFE pharma hose with Chemours (Dupont) Teflon PTFE 62 compound were tested in accordance with the below mentioned standards to assess state-of-the- art biocompatibility requirements. This includes ISO 10993 testing as well as USP class VI tests to evaluate toxicity systemically, intracutanously, and through implantation.

TESTING	STANDARD	RESULT
Hemolysis	ISO 10993-4 ISO 10993-12	Pass Test Report N° 21-0757-13
In-vitro Cytotoxicity	ISO 10993-12 ISO 10993-5 USP <87>	Pass Test Report N° 21-0757-06 & Test Report N° 21-0757-07 Test-No: 1527-4/15
USP Class VI **Intracutaneous Reactivity in the rabbit**	USP <88>	Pass Test Report N° 21-0757-03 Test-No: 1527-1/15
USP Class VI **Systemic Toxicity in the mouse**	USP <88> ISO 10993-11	Pass Test Report N° 21-0757-04 Test-No: 1527-2/15
USP Class VI **Implantation muscle in the rabbit**	USP <88>	Pass Test Report N° 21-0757-05 Test-No: 1527-3/15

Note:
AVIPURE®-WT hoses are not intended for use as an implant material. Not suitable for blood or human fluids.

2.7 Hose Printing

The PTFE pharma hose is printed in blue with the AVIPURE®-logo, size, lot number and manufacture date. The hose features the patented Low-Tack surface treatment providing enhanced technical and handling properties.

2.8 Extractable Profile

Extractables study with distilled water and ethanol for Chemours (Dupont) Teflon PTFE 62, in reference to test report 19CN00070 (NIAS evaluation found in the sample RdP10LA04400) dated 24 of May 2019, issued by 3A LABORATORI SRL.

The test materials were subjected to extraction in various solvents at controlled temperatures.

Extraction Medium 1)	Contact method	Total Contact Time [h]	Extraction Volume [ml]	Temperature Range 2) [°C]	Contact surface area [dm2]
Distilled water	Article filling	24	200	100	3.79
Ethanol at 95% (v/v)	Article filling	24	100	80	3.79

	Distilled water: Overall Migration		Ethanol at 95% (v/v): Overall Migration	
	mg/dm2	mg/kg	mg/dm2	mg/kg
Limit in reference to Reg. 10/2011	10	60	10	60
Test report n° 19LA04400	< 1	< 6	< 1	< 6

The results showed a global migration far from the limit defined by Reg. 10/2011 and subsequent amendments (10 mg/dm2 or 60 mg/kg).

2.9 Sterilization Compatibility

It is the responsibility of the user to validate a sterilization process with autoclave for silicone pharma hose with PTFE Chemours (Dupont) T62WT Inliner. The product will be delivered non-sterile.
Sterilization test Report No 21-0757-02 Biochem October 19th, 2021.

Sterilization with steam (autoclave or inline sterilization SIP up to 135 °C), is generally recommended. The suitability of the material must be evaluated by the user. Possible material damage depends on the sterilization conditions (temperature, pressure, and time).

Sterilization of PTFE pharma hose with multiple CIP/SIP-cycles at 135 °C does not impair fit, form or function of the products. The amount of the repetitions and the process conditions used are within the validation responsibility of the user. The user is obliged to examine the re-sterilizability under application-related conditions, since the number of resterilization cycles may be influenced by the flow medium/ cleaning agent and/ or mechanical stress applied throughout application lifetime. However, avintos has tested 300 sterilization cycles at 135°C without any visual impact on the tested hoses.

2.10 General Properties, Shelf Life and Storage

According to the current state of-the-art individual fisheyes due to raw material and processing, foreign material, dirt inclusions and air bubbles as well as contamination on the hose surface, like intrinsic particles and fluff, cannot be completely excluded.

The following shelf life is valid for the non-sterile, originally packed products.
A slight discoloration of the material might appear over storage time which may vary from batch to batch in intensity. This material related aging effect is common and does neither affect functionality nor material properties of PTFE pharma hose in the scope of specified physical properties as well as shelf-life.

The shelf life of the PTFE pharma hose in non-sterile condition and originally packed is 5 years. There is no substantial change of the specified physical, chemical, and physiological parameters of the hose material after that period of time.

The following storage conditions shall apply:

- Storage in original packaging
- Dry (Standard conditions 10 – 75% relative humidity)
- Temperature 15 - 25°C with short-term deviations 5 – 35°C
- Goods protected from moisture
- Goods protected from directly exposure to UV-light
- Not in the environment and in presence of chemicals, e.g. solvent and disinfectant

3 Functional Tests

3.1 Pressure Testing

The pressure ratings represent typical reference values for selected dimensions. The tests were conducted on a test bench in accordance with ISO 1402 at ambient conditions. The values are applicable for non-sterile as well as sterilized hose.

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Remarks:

- The bursting pressure of the AVIPURE® - WT hose is reduced by around 20% per temperature increase of 93°C until the maximum hose temperature is reached. The reduction is linear
- Pressure limit rates can be limited by used end connections
- Norm: ISO 1307 for dimensional tolerances
- Technical contents are subject to change with revision but without prior notice