

RENOLIT Nederland B.V.

Part of **RENOLIT** Healthcare

TECHNICAL DATA

COMPOUND	:	3222
PRODUCT	:	RENOLIT TRANSFUFOL SETA
POLYMER	:	PVC
MAIN APPLICATION AREAS	:	Blood bags and blood contact devices

PHYSICAL PROPERTY*	DIMENSION	VALUE	PROCEDURE
Tensile strength at break	MPa	25	ASTM D-882
Elongation at break	%	330	ASTM D-882
Tensile strength at 100% elongation	MPa	10	ASTM D-882
Shore-A Durometer hardness	-	86	ASTM D-2240
Break at cold temperature	°C	-24	ISO 8570
Density	g/cm ³	1.24	ASTM D-792
Water vapor transmission rate	g/(m ² .day)	4.9 (23°C, 100% RH)	ASTM F-1249
Oxygen permeability	cm ³ /(m ² .day.bar)	450 (23°C, 0% RH)	ASTM D-3985
Carbon dioxide permeability	cm ³ /(m ² .day.bar)	3500 (23°C, 0% RH)	ASTM F-2476
Recommended sealing method	:	Radio frequency, high frequency	
Recommended sterilization method	:	Steam (121 °C), ETO	
Formulation characteristics	:	European Pharmacopoeia grade, DEHP plasticizer No animal derived components	

This **RENOLIT** Healthcare product fulfils the test requirements of the relevant sections of the European and United States Pharmacopoeia, the relevant biocompatibility tests as per ISO 10993 as well as other relevant standards. Details can be found in the Pharmacopoeia Compliance and Biocompatibility Statement. Compliance with applicable regulations can be found in the Regulatory Status document for the product. These documents and the relevant test reports are available on request.

*Thickness test film 0.35 mm

2023/12

This technical information consists of typical product data and should not be used as a specification. Unless specified otherwise, all **RENOLIT** Healthcare film, tubing and compound materials can be stored for two years indoors under controlled environmental conditions and in the original closed containers. The ideal storage condition is 23 °C (73 °F) and 50% relative humidity in a well ventilated and dry facility. When ideal controlled environmental storage conditions are not possible, **RENOLIT** Healthcare materials should be stored in their original closed containers at temperatures between 0 - 40 °C (32 - 104 °F), relative humidity between 20 - 80% and protected from direct heat and sunlight (UV). Prior to the use of product exceeding 2 years in storage, it should be tested to confirm its usefulness for the intended application.

The data contained in this document are provided in good faith for the sake of general information. It is deemed to be accurate at the time of going into press. The purchaser or user is required to verify with our technical services whether any specific application is appropriate. Freedom of possession, use or marketing under intellectual rights or legal provisions or regulations, whether national or local, must be duly considered before use. Under no circumstances should any **RENOLIT** Healthcare film, tubing or compound be used in any cosmetic, reconstructive or any other temporary or permanent bodily implant application.

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