raumedic

Validation Package

SILMOTION
Silicone Pharma Tubing
made by RAUMEDIC

raumedic.com



For us the issue of the customer's approval is the proof of the functional efficiency respectively of the fitness of our articles, which the customer determined for the specification application within the scope of testing. The obligated quality of goods has to conform to the expressly stipulated performance features in written form only (e.g. Specifications, Technical Delivery Specification, drawings, markings and other data).
We only assume a warranty exceeding this stipulation of obligated quality for a specific application or a specific fitness, period of application or life period after passing of risk, if this is expressly agreed upon in written form; otherwise the risk of application and fitness is solely with the purchaser.

RAUMEDIC products and medical devices manufactured from these may not be sold or used in applications in the human body lasting more than 24 hours. No other guarantees are or will be given by RAUMEDIC.

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

1. Introduction

1.1 About RAUMEDIC

As a partner of the international medical technology and pharmaceutical industry, RAUMEDIC develops and produces components for customers, including tubing, catheters, and molded parts as well as complex groups of components and systems for a wide range of diagnostic and therapeutic uses. For the clinical areas of neuro-monitoring and traumatology, RAUMEDIC produces high-precision pressure-measurement sensors. The company is 100 percent family-owned.

RAUMEDIC Group

RAUMEDIC AG

CEO Stefan Seuferling	**CTO** Thomas Knechtel	**COO** Klaus Schabert	**CFO** Dr. Robert Schilling
Sales & Marketing	**Business Development**	**Supply Chain Management**	**Finance**
Human Resources	**Product Management**	**Logistics**	**Information Technology**
Strategy & Management Projects	**Product Development Compounds & Extrusions**	**Plant Münchberg**	**Clinical Products**
Project Office	**Product Development Assemblies**	**Plant Feuchtwangen**	
Legal, Compliance & IP	**Product & Process Development Silicone**	**Plant Zwönitz**	
	Process Development	**Industrial Engineering**	
	Materials Development	**Lean Management**	
	Quality Management	**International Project Management**	
	Regulatory Affairs		

The information in this document is subject to change without notice and should not be construed as a commitment by RAUMEDIC.

1.2 Security of Supply

The RAUMEDIC manufacturing plants operate under ISO 7 clean room conditions in order to offer flexibility and reliability to our customers worldwide. Consistent process performance is ensured by the ongoing qualification of all manufacturing processes and personnel.

RAUMEDIC pursues a multiple sourcing strategy for the Silicone Pharma Grade Silicone SIK8649. Different suppliers are used for this grade to ensure the security of supply. RAUMEDIC has validated the mechanical, physical and chemical equivalence and will use the sources in parallel according to the market situation. The used sources can be traced back via batch traceability at any time and fulfill the agreed specification.

1.3 cGMP Conformity

Consistent high quality of silicone tubing 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

RAUMEDIC is certified according to ISO 13485. The respective certificate can be found attached to this document in appendix A.1 Certificates.

2.0 Technical Specifications

2.1 Tubing Dimensions, Type and Part Numbers Overview

SILMOTION tubing coils made of Silicone SIK8649 are of dimensions between 1/32“ x 5/32“ (ID x OD) and 1“ x 1 3/8“ (ID x OD). The color of the tubing is natural without addition of color pigments (RAUMEDIC color no. 20900). All tubing coils are provided in double PE bags packaged in a cardboard box. Further dimensions upon request.

Dimension ID x OD	Tolerances		Coil length [m]	Printed / non-printed	Article code
	ID [mm]	WT (*OD) [mm]			
1/32" x 5/32" 0,8 mm x 4,0 mm	0,70 - 0,80	1,50 - 1,70	100	non-printed	818830-800
1/16“ x 3/16“ 1,6 mm x 4,8 mm	1,45 - 1,75	1,45 - 1,75	15	non-printed	818832-323
			15	printed	818832-324
			100	non-printed	818832-800
			100	printed	818832-801
3/32" x 7/32" 2,4 mm x 5,6 mm	2,20 - 2,60	1,40 - 1,80	100	non-printed	818816-800
1/8“ x 1/4“ 3,2 mm x 6,4 mm	3,00 - 3,40	1,40 - 1,80	15	non-printed	818834-323
			15	printed	818834-324
			100	non-printed	818834-800
			100	printed	818834-801
1/8" x 5/16" 3,2 mm x 7,9 mm	3,00 - 3,40	2,10 - 2,70	50	non-printed	818819-800
3/16" x 5/16" 4,8 mm x 7,9 mm	4,55 - 4,75	* 7,50 - 7,92	50	non-printed	818847-800
3/16" x 3/8" 4,8 mm x 9,5 mm	4,60 - 5,00	2,10 - 2,70	50	non-printed	819040-800
1/4“ x 3/8“ 6,4 mm x 9,5 mm	6,10 - 6,70	1,40 - 1,80	15	non-printed	818835-323
			15	printed	818835-324
			50	non-printed	818835-800
			50	printed	818835-801
1/4“ x 7/16“ 6,4 mm x 11,1 mm	6,10 - 6,70	2,10 - 2,70	15	non-printed	818841-323
			15	printed	818841-324
			50	non-printed	818841-800
			50	printed	818841-801
5/16“ x 1/2“ 7,9 mm x 12,7 mm	7,62 - 7,92	2,20 - 2,60	15	non-printed	818035-323
			15	printed	818035-324
			30	non-printed	818035-800
			30	printed	818035-801
5/16" x 3/4" 7,9 mm x 19,1 mm	7,62 - 7,92	5,30 - 5,90	25	non-printed	818806-800
3/8" x 1/2" 9,5 mm x 12,7 mm	9,40 - 9,80	1,40 - 1,80	50	non-printed	818880-800
3/8" x 9/16" 9,5 mm x 14,3 mm	9,40 - 9,80	2,10 - 2,70	25	non-printed	818762-800

Dimension ID x OD	Tolerances		Coil length [m]	Printed / non-printed	Article code
	ID [mm]	WT (*OD) [mm]			
3/8“ x 5/8“ 9,5 mm x 15,9 mm	9,40 - 9,80	2,90 - 3,30	15	non-printed	818842-323
			15	printed	818842-324
			25	non-printed	818842-800
			25	printed	818842-801
1/2“ x 3/4“ 12,7 mm x 19,1 mm	12,50 - 13,50	2,70 - 3,30	15	non-printed	818844-323
			15	printed	818844-324
			25	non-printed	818844-800
			25	printed	818844-801
1/2" x 7/8" 12,7 mm x 22,2 mm	12,20 - 12,70	4,45 - 4,75	20	non-printed	818828-800
3/4“ x 1“ 19,1 mm x 25,4 mm	18,50 - 19,70	2,85 - 3,45	15	non-printed	818839-323
			15	non-printed	818839-800
			15	printed	818839-801
3/4“ x 1 1/8“ 19,1 mm x 28,6 mm	18,50 - 19,70	4,45 - 5,05	15	non-printed	818840-323
			15	non-printed	818840-800
			15	printed	818840-801
1“ x 1 3/8“ 25,4 mm x 34,9 mm	24,60 - 26,20	4,40 - 5,20	10	non-printed	818846-323
			10	non-printed	818846-800
			10	printed	818846-801

2.2 Material Information

SILMOTION silicone pharma tubing is made of the material grade Silicone SIK8649, a high purity silicone rubber suitable for pharma applications. Chemically Silicone SIK8649 is an addition cross-linked hot vulcanisate based on vinyl methyl dimethyl polysiloxane using silicic acid fillers and a platinum catalyst.

SILMOTION tubing can be used continuously in a temperature range from -60 °C (-76 °F) to +200 °C (+392 °F) without loosing its integrity or deterioration of its chemical | physiological properties

The material Silicone SIK8649 shows good resistance to water up to 100 °C and to low-pressure steam up to 135 °C. Steam from higher temperatures leads to degradation, especially after prolonged exposure.

Silicone SIK8649 has good resistance to weak acids and alkalis. However, the material will degrade by strong acids and alkalis, which will be promoted at higher temperatures.
The resistance is strongly dependent on the polar or non-polar character of the contact medium. While there is almost no swelling in polar contact media (e.g. water/alcohol), non-polar contact media (e.g. petrol/oil) cause medium to strong but reversible swelling.

The surface is coated in a plasma process. This coating provides a less sticky surface of these silicone tubing (Low Tack - see also 2.7) in comparison with common non-coated silicone products. Silicone tubing is colourless transparent or translucent.

2.3 Material Compliance

Based on our experience and knowledge about the materials and production processes the material formulation complies with / does not contain:

- Bisphenol A (BPA)
- Latex
- Phthalates
- Endocrine disruptors
- Ozone depleting substances (Regulation (EC) No 1005/2009)
- Perfluorinated chemicals (PFOA, PFOS)
- Persistent Bioaccumulative Toxins (PBTs)
- Persistent Organic Pollutants (POPs) (Regulation (EU) 2019/1021)
- Genetically Modified Organisms (GMO)
- Animal derived materials (Materials which present BSE/TSE risks)
- Conflict minerals (Dodd-Frank Act, Section 1502)
- RoHS (Directive 2011/65/EU, Directive (EU) 2015/863)
- Heavy Metals (CONEG, Directive 94/62/EC)
- CMR substances (Regulation (EC) No 1272/2008)
- Substances of Very High Concern (SVHC) as identified under article 33 of Regulation (EC) No 1907/2006 (REACH or substances listed in Annex XIV and Annex XVII
- Nanomaterials (acc. to the definition Medical Device Regulation (EU) 2017/745) as intentionally added components above threshold limits stated in aforementioned Regulations, Directives or Laws

However, the raw materials used, and our final product(s) are not analyzed for the presence of traces of the above-mentioned substances.

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

Property	Norm	SIK8649
Shore hardness A	ISO 48-4	60 ± 5
Density (g/cm³)	ISO 1183	1.15
Tear strength (MPa)	ISO 527	≥ 8.0
Elongation at break (%)	ISO 527	≥ 500
Compression Set (%, 22h / 175 °C)	ISO 815-1 type B	≤ 15 %

The physical properties of the raw material were determined on standard test specimen.
The specified values represent guide values.

2.5 Physico-Chemical Properties

European Pharmacopoeia: 3.1.9 & FDA regulation 21CFR, § 177.2600

Test results | SILMOTION tubing in silicone rubber meets the requirements of the European Pharmacopoeia 3.1.9. and regulation 21 CFR, § 177.2600. The test methods, limits and results are those described by the E.P. monograph and listed in the table below.

Test Description	E.P. 3.1.9 Limits	Results on silicone tubing: Pass or Fail
Appearance of Solution	Colourless	Pass
Acidity	≤ 2.5 mL NaOH 0.01M	Pass
Alkalinity	≤ 1.0 mL HCl 0.01M	Pass
Reducing Substances	≤ 1 mL	Pass
Substances Soluble in Hexane	≤ 15 mg	Pass
Volatile Matter	< 2 %	Pass
Mineral Oils	< 1 ppm	Pass
Platinum	< 30 ppm	Pass

USP ‹661› - Containers, Physico-chemical Tests – Plastic

Test results | The SILMOTION tubing meets the USP ‹661› requirements when sterilized at 50 kGy with and without aging conditions corresponding to a shelf life of 5 years.

Test Description	USP ‹661› Limits	Results on silicone tubing: Pass or Fail
Non Volatile Residue	< 15 mg	Pass
Residue on Ignition	< 5 mg	Pass
Heavy Metals	< 1 ppm	Pass
Buffering Capacity	< 10 mL	Pass

2.6 Biocompatibility

Samples of SILMOTION pharma tubing 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	Pass
In-vitro Cytotoxicity	ISO 10993-5	Pass
Implantation	ISO 10993-6	Pass
Sensitization	ISO 10993-10	Pass
Pyrogenicity	Eur. Ph.	Pass
USP Class VI – Intracutaneous Reactivity (Irritation Rabbit) [1)]	USP ‹88›	Pass
USP Class VI – Systemic Toxicity (Mice) [1)]	USP ‹88›	Pass
USP Class VI – Implantation 7 days (Rabbit) [1)]	USP ‹88›	Pass

[1)] Tests were performed on gamma irradiated samples (50 kGy)

2.7 Tubing Printing

The tubing is available unprinted, with a standardized printing (refer table point 2.1) or a customized printing.
The standardized printing text is defined as follows:
„SILMOTION A“ x B“ MADE BY RAUMEDIC LOT XXXXXXXX“
A - Inner diameter in inch
B - Outer diameter in inch

RAUMEDIC biopharma silicone tubing features the patented Low-Tack surface treatment providing enhanced technical and handling properties.

The biocompatibility of the ink was proven by successfully performed ISO 10993-5 and USP ‹88› testing.

2.8 Extractable Profile

The study on the extractables profile for SILMOTION pharma tubing was performed according to BPOG “BioPhorum Best Practices Guide for Extractables Testing of Polymeric Single-Use Components Used in biopharmaceutical Manufacturing” released in April 2020. The assessment on gamma-irradiated and autoclaved tubing will be provided upon request.

2.9 Sterilization Compatibility

It is the responsibility of the user to validate a sterilization process with autoclave for SILMOTION tubing.

SILMOTION tubing is produced for single use. The product will be delivered non-sterile.

Sterilization with gas (ethylene oxide, ETO), steam (up to 135 °C), gamma or X-rays (Dose: max. 50 kGy) is generally recommended. The suitability of the material must be evaluated by the user. Possible material damage depends on the sterilization conditions (temperature, pressure, energy, time, packaging unit and distance to the radiation source).

Multiple sterilization is not recommended, neither with different nor the same sterilization method.

However, sterilization of SILMOTION tubing 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.

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 tubing 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 Silicone SIK8649 in the scope of specified physical properties as well as shelf-life.

The shelf life of the tubing made of RAUMEDIC Silicone SIK8649 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 tubing 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 tubing.

Tube size ID (“) x OD (“)	Failure Pressure [bar]	Max. recommended working pressure [bar]
1/16 x 3/16	≥ 6,0	≤ 1,5
1/8 x 1/4	≥ 5,0	
1/4 x 3/8	≥ 3,0	
1/4 x 7/16	≥ 4,0	
3/8 x 5/8	≥ 4,5	
1/2 x 3/4	≥ 4,5	
3/4 x 1	≥ 3,0	
3/4 x 1 1/8	≥ 3,0	
1 x 1 3/8	≥ 3,0	

The specified pressures were determined on tubes in the condition as they are delivered by RAUMEDIC. With regards to pressure testing of silicone tubing RAUMEDIC does not use the common terminology of burst but failure pressures. The reason lies within the elastomeric behavior of silicone, which causes a balloon-like inflation of the tube after reaching the failure pressure. At this specific point, the tube is no longer able build up pressure but inflates uncontrollably. Failure pressures and working pressures of silicone tubes can be significantly influenced by several determinants like flow media, operating temperature and time, shore hardness, connection technology and sterilization conditions. For this reason, the failure pressure is to be considered as typical reference value while representing the minimum requirement for each dimension. The maximum working pressures as recommended by RAUMEDIC represent values that have been determined considering the influencing factors mentioned above to the best of our knowledge. The failure and working pressures stated by RAUMEDIC do not release the customer from process validation under application conditions since it is not possible to test all variables within the scope of the type tests performed.

3.2 Pumping Lifetime

Reference pumping lifetime for selected dimensions to assess the mechanical resistance of the tubing under pumping conditions. The stated values are based on external test data. The tests were conducted in a peristaltic roller pump. The tubing was pumping water at ambient temperature between 2 tanks mimicking recirculation conditions. The test was stopped and time measured at tubing break resulting in leak.

Tube size ID (“) x OD (“)	Pump Speed [rpm]	Pumping Lifetime [h]
1/4 x 7/16	210	
1/2 x 3/4	310	› 70
3/4 x 1 1/8	310	

3.3 Flow Rate Data

The objective of this test was to assess the maximum flow rate of selected dimensions by means of an peristaltic roller pump. The stated values are based on external test data.

Tube size ID (“) x OD (“)	Pump Speed [rpm]	Flow Rate [L/min] *
1/4 x 7/16		› 1,2
1/2 x 3/4	310	› 8,9
3/4 x 1 1/8		› 20,0

*The measured values given are empirically determined guide values .

Additional Documents

A.1 Certificates – ISO 13485:2016

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 053268 0081 Rev. 01

Holder of Certificate: **RAUMEDIC AG**
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design, development, production and sales of**
- systems, components and semi-finished products made from polymer materials for medical devices and medical accessories, based on extrusion, injection moulding and assembly techniques
- precision measurement catheters and accessories
- compounds for the manufacturing of products for medical applications

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 053268 0081 Rev. 01

Report No.: 713204491

Valid from: 2022-04-06
Valid until: 2025-03-31

Date, 2022-04-06

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 053268 0081 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

RAUMEDIC AG
Hermann-Staudinger-Strasse 2, 95233 Helmbrechts, GERMANY

See Scope of Certificate

RAUMEDIC AG
Crailsheimer Strasse 34, 91555 Feuchtwangen, GERMANY

See Scope of Certificate

RAUMEDIC AG
Am Mühlgraben 10, 08297 Zwönitz, GERMANY

See Scope of Certificate

Parameters: -

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A.2 Certificates – ISO 15378:2018

bavaria certification

CERTIFICATE

RAUMEDIC
Lifeline to Health

It is hereby certified, that the company

Raumedic AG

Hermann-Staudinger-Straße 2
95233 Helmbrechts, Germany

has implemented and applied a Management System in accordance to the Standard

DIN EN ISO 15378:2018

Certified Scope:
Design, development and production of systems, components, semi finished products made from polymer materials as primary packaging materials for medicinal products based on extrusion, injection moulding and assembly techniques.

This certificate is valid from 01-15-2021 until 01-14-2024.

certificate-no.: K1068/PMA/10.20

Evidence has been provided with audit report no. K1068/10054.

bavaria certification GmbH
Oberschneiding, 01-15-2021

DAkkS Deutsche Akkreditierungsstelle D-ZM-19687-01-00

bavaria certification GmbH
Straubinger Straße 19
94363 Oberschneiding
www.bavaria-cert.com

A.3 Certificates – ISO 50001:2018

CERTIFICATE

ISO 50001:2018

DEKRA Certification GmbH hereby certifies that the organization

RAUMEDIC AG

Scope of certification:

Design, development and production of medical devices, systems, components and semi-fishes products made from polymer materials for medical devices and medical accessories.

Certified location:

Hermann-Staudinger-Straße 2, 95233 Helmbrechts, Deutschland
(further locations see annex)

has established and maintains an energy management system according to the above mentioned standard. The conformity was adduced with audit report no. A20081095.

Certificate registration no.:	181214123/2	Certificate valid from:	2020-12-30
Validity of previous certificate:	2020-12-29	Certificate valid to:	2023-12-29

Language translation

Dr. Gerhard Nagel
DEKRA Certification GmbH, Stuttgart, 2020-11-30

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra.de/audits

Annex to the Certificate No. 181214123/2

valid from 2020-12-30 to 2023-12-29

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	RAUMEDIC AG	Hermann-Staudinger-Straße 2 95233 Helmbrechts Deutschland	See page 1
	at the following locations / at the companies at the following locations		**Scope of certification**
1.	RAUMEDIC AG	Crailsheimer Str. 34 91555 Feuchtwangen Deutschland	Production of medical devices, medical subassembly and compounds.
2.	RAUMEDIC AG	Am Mühlgraben 10 08297 Zwönitz Deutschland	Design, development and production of medical devices.

Dr. Gerhard Nagel
DEKRA Certification GmbH, Stuttgart, 30.11.2020

A.4 Documentation – Material Safety Data Sheet

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SIK5XXX, SIK6XXX, SIK8XXX (X=0-9)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 12/5/2023 Revision date: 12/5/2023 Supersedes version of: 1/15/2020 Version: 2.00

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name : SIK5XXX, SIK6XXX, SIK8XXX (X=0-9)
Type of product : Polymer

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Extrusion, Injection molding

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier
RAUMEDIC AG
Hermann Staudinger-Straße 2
DE– 95233 Helmbrechts
Germany
T +49-(0) 92 52 / 3 59-0 - F +49-(0) 92 52 / 3 59-10 00
info@RAUMEDIC.com - www.RAUMEDIC.com

Email competent person
sds@kft.de

1.4. Emergency telephone number

Emergency number : GIZ-Nord, Göttingen
Germany
+49 551 19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

PBT: not relevant – no registration required
vPvB: not relevant – no registration required
Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments	:	Vinyl methyl dimethyl polysiloxane using silicic acid fillers Safety data sheet is for the processed (tempered) product.

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	:	In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	:	Remove person to fresh air and keep comfortable for breathing. Inhalation of product is unlikely.
First-aid measures after skin contact	:	Wash skin with plenty of water. Get medical advice if skin irritation persists.
First-aid measures after eye contact	:	Eye contact is unlikely. If particles get into the eyes, remove as customary for foreign bodies. Rinse eyes with water as a precaution.
First-aid measures after ingestion	:	Spit. Rinse mouth out with water. Do not induce vomiting. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	:	Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	:	Strong water jet.

5.2. Special hazards arising from the substance or mixture

Reactivity in case of fire	:	Decompose in hydrogen which is fire and explosion generator.
Hazardous decomposition products in case of fire	:	Toxic fumes may be released. Carbon monoxide. Carbon dioxide. Silicon oxide. hydrogen.

5.3. Advice for firefighters

Firefighting instructions	:	If there is a fire close by, use suitable extinguishing agents. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	:	Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	:	Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	:	Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.1.1. For non-emergency personnel

Emergency procedures	:	Prohibit unauthorized persons. Ventilate spillage area. Do not breathe mist, vapours, spray. Keep away from sources of ignition. Spill area may be slippery.

6.1.2. For emergency responders

Protective equipment	:	Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Avoid sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	:	Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Clean contaminated surfaces with an excess of water.
Other information	:	Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	:	Product may release hydrogen gas. Increased storage temperatures will accelerate this process.
Precautions for safe handling	:	Ensure good ventilation of the work station. Wear personal protective equipment. Do not breathe mist, vapours, spray. Keep away from sources of ignition - No smoking. Avoid the build-up of electrostatic charge.
Hygiene measures	:	Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	:	Store in original container. Store in a well-ventilated place. Keep cool. Protect from moisture.
Incompatible materials	:	Do not store in brand new glass containers with an alkaline surface.
Heat and ignition sources	:	Keep away from heat and direct sunlight.
Information about storage in one common storage facility	:	Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:
Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing. EN 13034. EN ISO 13688

Hand protection:
In case of repeated or prolonged contact wear gloves. Nitrile rubber. Butyl rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. P2. EN 143. Short term exposure. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

Other information:
Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Diverse.
Appearance	:	Paste.
Odour	:	weak.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not applicable
Explosive properties	:	Product is not explosive.
Oxidising properties	:	Non oxidizing.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	> 150 °C
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
Solubility	:	Water: Insoluble
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available

Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Contact with metals produces hydrogen gas which may form explosive mixtures with air.

10.4. Conditions to avoid

Protect from moisture. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5. Incompatible materials

Strong acids. alkalis. Oxidizing agent. Alcohol. Water, humidity.

10.6. Hazardous decomposition products

Hydrogen. Formaldehyde.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	:	Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	:	Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	:	Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	:	Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	:	Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	:	Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	:	Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	:	Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	:	Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	:	Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long–term (chronic) : Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

SIK5XXX, SIK6XXX, SIK8XXX (X=0-9)	
Persistence and degradability	Product is practically not biodegradable.

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

SIK5XXX, SIK6XXX, SIK8XXX (X=0-9)
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. Do not dispose of with domestic waste. Do not discharge into drains or the environment. European waste catalogue.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

Additional information : Packaging must be completely emptied.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not regulated

Transport by sea
Not regulated

Air transport
Not regulated

Inland waterway transport
Not regulated

Rail transport
Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

National Rules and Recommendations : TRGS 510: Storage of hazardous substances in non-stationary containers.
Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).
Storage class (LGK, TRGS 510) : LGK 10 - Combustible liquids.
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	**Changed item**	**Change**	**Comments**
	General revision		

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : European Chemicals Agency, http://echa.europa.eu/. Information provided by the manufacturer.

Department issuing data specification sheet: : KFT Chemieservice GmbH
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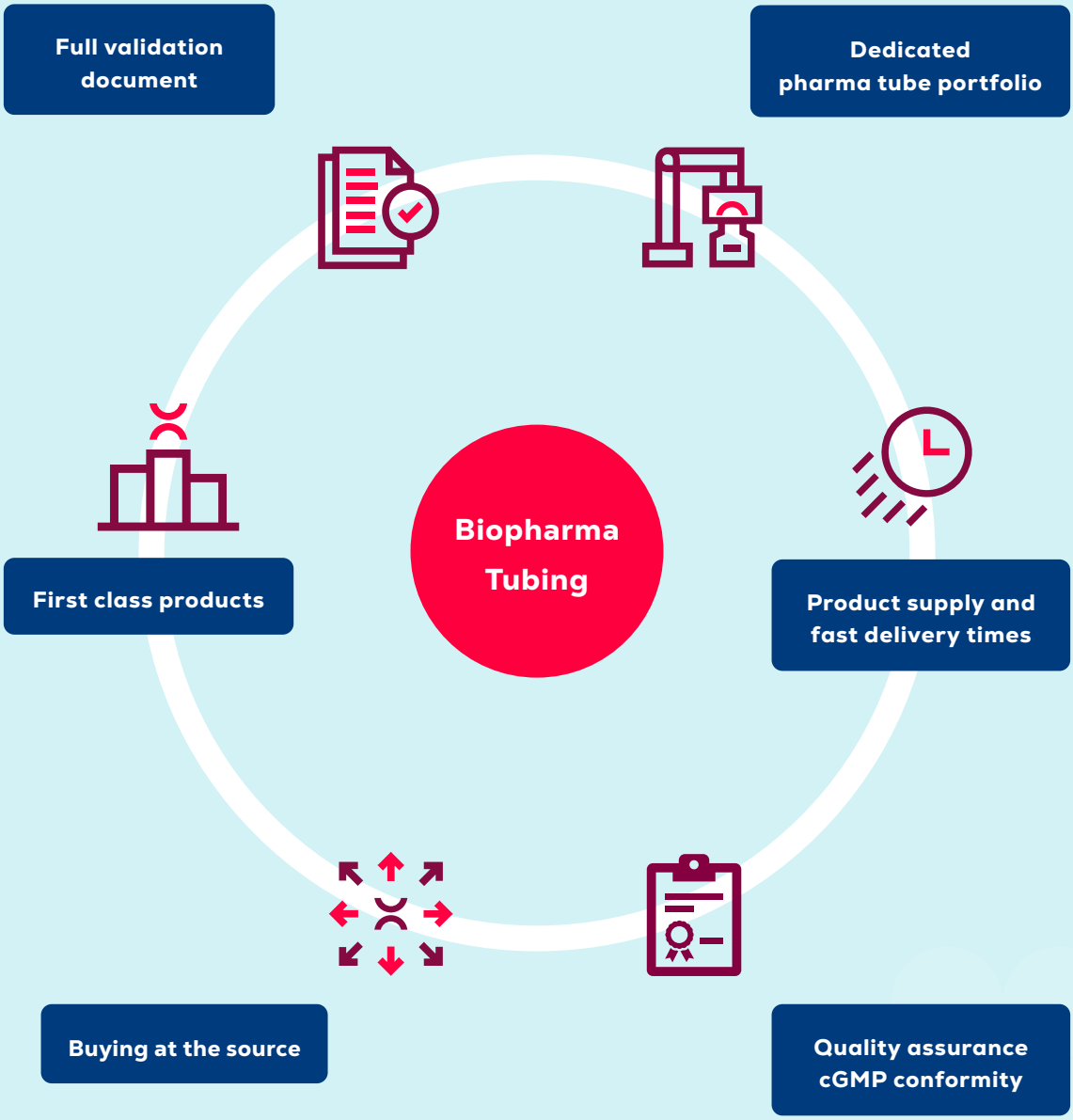
SDS Service: +49 6155 8981-522

Contact person : Dr. Christian Rank

KFT SDS EU 00 - Version 23.1

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

RAUMEDIC biopharma tubings offer significant advantages



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Executive Board: Stefan Seuferling (Chairman) – Thomas Knechtel – Klaus Schabert – Dr. Robert Schilling
Chairman of the Supervisory Board: Jürgen Werner

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