raumedic

Validation Package

THERMMOTION
TPE 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 in Europe and the US 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.

1.3 cGMP Conformity

Consistent high quality of TPE 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

THERMMOTION tubing coils made of TPE SRT629 are of dimensions between 1/8" x 1/4" (ID x OD) and 3/4" x 1 1/8" (ID x OD). The color of the base tubing is natural without addition of color pigments (RAUMEDIC color no. 90600). Additionally all tubings have an extruded color stripe, the color of the stripe depends on the tubing dimension (see table below). All tubing coils are provided in double PE bags packaged in a cardboard box.

Dimension ID x OD	Tolerances		Color stripe	Coil length [m]	Printed / non-printed	Article code
	Inner diameter [mm]	Wall thickness [mm]				
1/8" x 1/4" 3,2 mm x 6,4 mm	3,10 - 3,30	1,50 - 1,70	Yellow	200	non-printed	062016-800
				200	printed	062016-801
1/4" x 3/8" 6,4 mm x 9,5 mm	6,25 - 6,55	1,50 - 1,70	Orange	125	non-printed	062017-800
				125	printed	062017-801
1/4" x 7/16" 6,4 mm x 11,1 mm	6,25 - 6,55	2,25 - 2,45	Red	100	non-printed	062018-800
				100	printed	062018-801
3/8" x 5/8" 9,5 mm x 15,9 mm	9,35 - 9,65	3,05 - 3,35	White	15	non-printed	062019-022
				15	printed	062019-024
				50	non-printed	062019-800
				50	printed	062019-801
1/2" x 3/4" 12,7 mm x 19,1 mm	12,40 - 12,80	3,05 - 3,35	Grey	15	non-printed	062020-022
				15	printed	062020-024
				30	non-printed	062020-800
				30	printed	062020-801
3/4" x 1" 19,1 mm x 25,4 mm	18,75 - 19,25	3,05 - 3,35	Blue	15	non-printed	062021-022
				15	printed	062021-024
				20	non-printed	062021-800
				20	printed	062021-801
3/4" x 1 1/8" 19,1 mm x 28,6 mm	18,75 - 19,25	4,55 - 5,05	Black	15	non-printed	062022-022
				15	printed	062022-024
				20	non-printed	062022-800
				20	printed	062022-801

2.2 Material Information

THERMMOTION pharma tubing is made of the material grade SRT629, a high purity thermoplastic elastomer containing FDA approved ingredients* suitable for pharma applications. Chemically TPE SRT629 is an natural, synthetic thermoplastic rubber, based on an elastomer modified polypropylene, containing synthetic oil.

The material TPE SRT629 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. TPE SRT 629 has a good chemical resistance to water or aqueous solutions including acids and bases. In general, the resistance is limited in the case of permanent contact with oils or oil/water emulsions and alcohols. Thus, the resistance depends on the application conditions (e.g. temperature, duration). However, TPE SRT629 is not resistant to organic solvents.

The material can be used continuously in a temperature range from -55°C (-67°F) to +135°C (275°F) without losing its integrity or deterioration of its chemical | physiological properties.

*If you require more details, please contact your responsible sales contact.

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)
- Natural rubber latex
- Phthalates (Directive 2005/84/EC; 199/815/EC)
- Endocrine disruptors
- Ozone depleting substances (Regulation (EC) No 1005/2009)
- Perfluorinated chemicals (PFOA, PFOS, PFT)
- Persistent Bioaccumulative Toxins (PBTs)
- Persistent Organic Pollutants (POPs) (Regulation (EU) 2019/1021)
- Genetically Modified Organisms (GMO)
- Materials which present BSE/TSE risks
- Conflict minerals (Dodd-Frank Act, Section 1502)
- RoHS (Directive 2011/65/EU, Directive (EU) 2015/863/EC)
- 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 and associated materials 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	SRT629
Shore hardness A	ISO 48-4	60 ± 5
Density (g/cm³)	ISO 1183	0.90 ± 0.02
Stress at break (MPa)	ISO 527	≥ 5
Strain at break	ISO 527	≥ 450
Compression Set (%, 24h/40 °C)	ISO 815-1 type B	40

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

2.5 Physico-Chemical Properties

ISO 3826-1

The chemical properties of TPE SRT629 are evaluated in accordance with ISO 3826-1.

Test Description	DIN EN ISO 3826-1 Limits	Results on TPE tubing: Pass or Fail
Oxidizable components	≤ 1,5 ml	Pass
Acidity	≤ 0,4 ml	Pass
Alkalinity	≤ 0,8 ml	Pass
Evaporation residue	≤ 5 mg	Pass
Tin	≤ 0,1 mg/L	Pass
Lead	≤ 1,0 mg/L	Pass
Cadmium	≤ 0,1 mg/L	Pass
Barium	≤ 1,0 mg/L	Pass

USP ‹661›

The THERMMOTION tubing meets the USP requirements when sterilized at 50 kGy with and without aging conditions corresponding to a shelf life of 5 years.

Condition	Norm	Conclusion
50 kGy/t = 0	USP 37 – NF32 ‹661›	Compliant
50 kGy/t = 3 y	USP 37 – NF32 ‹661›	Compliant
AC/t = 0	USP 37 – NF32 ‹661›	Compliant
AC/t = 3 y	USP 37 – NF32 ‹661›	Compliant
NS/t = 5 y	USP 37 – NF32 ‹661›	Compliant

2.6 Biocompatibility

Testing	Standard	Result
Hemolysis	ISO 10993-4	Pass
In-Vitro Cytotoxicity	ISO 10993-5	Pass
USP Class VI – Intracutaneous Reactivity (Irritation Rabbit)	USP‹88›	Pass
USP Class VI – Systemic Toxicity (Mice)	USP‹88›	Pass
USP Class VI – Implantation 7 days (Rabbit)	USP‹88›	Pass

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:
„THERMMOTION A“ x B“ MADE BY RAUMEDIC LOT XXXXXXXX“
A - Inner diameter in inch
B - Outer diameter in inch

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 THERMMOTION 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 THERMMOTION tubing.

THERMMOTION tubing is produced for single use. The product will be delivered non-sterile. Sterilization with gas (ethylene oxide, ETO), steam (up to 123 °C), X-rays (Dose: max. 50kGy) and gamma 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 THERMMOTION tubing with multiple CIP/SIP-cycles at 123 °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 re-sterilization 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 technology, isolated inclusions due to raw material and processing, like gel particles, specks and gas bubbles cannot be completely excluded, so that inhomogenities and short-term deviations of dimensions inevitably may occur. Their number may vary from batch to batch.

Also, cannot be excluded an occasional occurrence of production-related marks and streaks.

A slight discoloration of the material might appear over storage time and/ or after sterilization 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 TPE SRT629 in the scope of specified physical properties as well as shelf-life.

The shelf life of the tubing made of TPE SRT629 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]
1/8 x 1/4	≥ 5,5	≤ 1,0
1/4 x 3/8	≥ 3,0	
1/4 x 7/16	≥ 4,5	
1/2 x 3/4	≥ 4,5	
3/4 x 1	≥ 2,5	
3/4 x 1 1/8	≥ 3,5	

The specified pressures were determined on tubes in the condition as they are delivered by RAUMEDIC. With regards to pressure testing of TPE tubing RAUMEDIC does not use the common terminology of burst but failure pressures. The reason lies within the elastomeric behavior of TPE, 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 TPE 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	220	289
1/2 x 3/4	320	165
3/4 x 1 1/8	320	100

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	220	1,5
1/2 x 3/4	320	12
3/4 x 1 1/8	320	21

*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. 02

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

Certification Mark:

TÜV SÜD
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
- dosing systems with 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. 02

Report No.: 713282560

Valid from: 2024-02-16
Valid until: 2025-03-31

Date, 2024-02-16

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. 02

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

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

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
- dosing systems with accessories

RAUMEDIC AG
Hermann-Staudinger-Strasse 6, 95233 Helmbrechts, GERMANY

Production and sales of
- systems, components and semifinished products made from polymer materials for medical devices
and medical accessories, based on extrusion and assembly techniques

RAUMEDIC AG
Crailsheimer Strasse 34, 91555 Feuchtwangen, GERMANY

Production and sales of
- components and semi-finished products made from polymer materials for medical devices and medical accessories, based on extrusion
- compounds for the manufacturing of products for medical applications

RAUMEDIC AG
Am Mühlgraben 10, 08297 Zwönitz, GERMANY

Design, development, production and sales of
- systems, components and semi-finished products made from polymer materials for medical devices and medical accessories, based on assembly techniques
- precision measurement catheters and accessories

Parameters: ./.

A.2 Certificates – ISO 15378:2018

bavaria certification

CERTIFICATE

raumedic

It is hereby certified, that the company

Raumedic AG

D- 95233 Helmbrechts, Hermann-Staudinger-Str. 2

has implemented and applied a Management System in accordance with 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.

This certificate is valid from 15.01.2024 until 14.01.2027.

Certificate-No.: K1068/PMA/09.23

Evidence has been provided with audit report no. K1068/P1011201.

bavaria certification GmbH
Oberschneiding, 12.12.2023

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

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

Hermann-Staudinger-Straße 2, 95233 Helmbrechts, Germany

for the 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.

(sites see annex)

has established and maintains an energy management system according to the above mentioned standard.
The conformity was adduced with audit report no. A23051471.

Certificate registration no.:	181214123/3
Validity of previous certificate:	2023-12-29
Certificate valid from:	2023-12-30
Certificate valid to:	2026-12-29

Language translation

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15

Dr. Rolf Krökel
DEKRA Certification GmbH, Stuttgart, 2023-12-07

Annex to the Certificate No. 181214123/3

valid from 2023-12-30 to 2026-12-29

The following sites / organizations belong to the certificate above:

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

Dr. Rolf Krökel
DEKRA Certification GmbH, Stuttgart, 2023-12-07

A.4 Documentation – Material Safety Data Sheet

RAUMEDIC
Lifeline to Health

PP6XXX, SBXXX, SRTXXX (X= 0-9)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)
Date of issue: 1/13/2020 Revision date: 1/13/2020 Version: 1.00

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

1.1. Product identifier

Trade name : PP6XXX, SBXXX, SRTXXX (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
Professional

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
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

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.
No labelling applicable

2.3. Other hazards

Other hazards not contributing to the classification : Risk of thermal burns on contact with molten product.
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : polymer mixture

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 case of doubt or persistent symptoms, consult always a physician.

First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact : After contact with the molten product, cool rapidly with cold water. Do not pull solidified product away from the skin. 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

Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Nitrogen oxides.

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 : Avoid dust formation. 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 dust, spray, fume. 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 sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : If melted: allow liquid to solidify before taking it up. 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	: Dust could form explosive mixtures with air.
Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with the heated or melted product. Avoid dust formation. Do not breathe dust, fume, 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 a well-ventilated place. Keep container tightly closed. Keep cool. Keep away from heat and direct sunlight. Protect from moisture. Avoid the build-up of electrostatic charge.
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

PP6XXX, SBXXX, SRTXXX (X= 0-9)	
Germany - Occupational Exposure Limits (Generic OEL data)	
	The general dust limit values of 1.25 mg/m³ for the alveolar (A-dust) and 10 mg/m³ for the inhalable (E-dust) fraction must be observed. A single layer mean value must not exceed the value of 3 mg/m³ for the A-dust fraction. For details see TRGS 900.

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:
In case of repeated or prolonged contact wear gloves. EN 374. For undissolved solid substances following materials may be suitable: Butyl rubber, Chloroprene rubber, Nitrile rubber, Fluoroelastomer (FKM). In the event of contact with molten product : Heat resistant gloves. 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
Eye protection:
In case of dust production: protective goggles. Not required for normal conditions of use. EN 166
Skin and body protection:
Wear suitable protective clothing. EN 340
Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. If dust are formed : P3. In the event of thermal decomposition : Filter: B E P3. 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. For details on application requirements and maximum application concentrations, please refer to DGUV regulation 112-190 - Use of breathing apparatus.

Environmental exposure controls:

Avoid sub-soil penetration. Do not allow into drains or water courses. Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use. Always wash hands after handling the product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid

Appearance	: Granulate.
Colour	: Diverse.
Odour	: characteristic.
Odour threshold	: No data available
pH	: Not applicable
Relative evaporation rate (butylacetate=1)	: Not applicable
Relative evaporation rate (ether=1)	: Not applicable
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not self-igniting
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: Not applicable
Relative vapour density at 20 °C	: Not applicable
Relative density	: No data available
Solubility	: Water: Insoluble
Log Pow	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosive properties	: Product is not explosive. Dust may form flammable and explosive mixture with air.
Oxidising properties	: Non oxidizing.
Lower explosive limit (LEL)	: Not applicable
Upper explosive limit (UEL)	: Not applicable

9.2. Other information

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.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong acids. Strong alkalis. Oxidizing agent.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition can lead to the release of irritating gases and vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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) pH: Not applicable

Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: Not applicable
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. Not relevant)
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Based on available data, the classification criteria are not met.
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

PP6XXX, SBXXX, SRTXXX (X= 0-9)	
Persistence and degradability	The product has not been tested.

12.3. Bioaccumulative potential

PP6XXX, SBXXX, SRTXXX (X= 0-9)	
Bioaccumulative potential	The product has not been tested.

12.4. Mobility in soil

PP6XXX, SBXXX, SRTXXX (X= 0-9)	
Ecology - soil	The product has not been tested.

12.5. Results of PBT and vPvB assessment

PP6XXX, SBXXX, SRTXXX (X= 0-9)
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.
Product/Packaging disposal recommendations	: Recycle or dispose of in compliance with current legislation.
Ecology - waste materials	: Avoid release to the environment.
European List of Waste (LoW) code	: 07 00 00 - WASTES FROM ORGANIC CHEMICAL PROCESSES 07 02 00 - wastes from the MFSU of plastics, synthetic rubber and man-made fibres 07 02 13 - waste plastic

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
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. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

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.

15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

Storage class (LGK) : LGK 11 - Combustible solids

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Other information, restrictions and prohibition regulations : TRGS 510: Storage of hazardous substances in non-stationary containers
TRGS 900: Occupational Exposure Limits

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

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
vPvB	Very Persistent and Very Bioaccumulative
	CAS (Chemical Abstracts Service) number
TLM	Median Tolerance Limit

Data sources : ECHA (European Chemicals Agency). MSDS of the supplier.

Department issuing data specification sheet: : KFT Chemieservice GmbH
Im Leuschnerpark. 3 64347 Griesheim
Germany

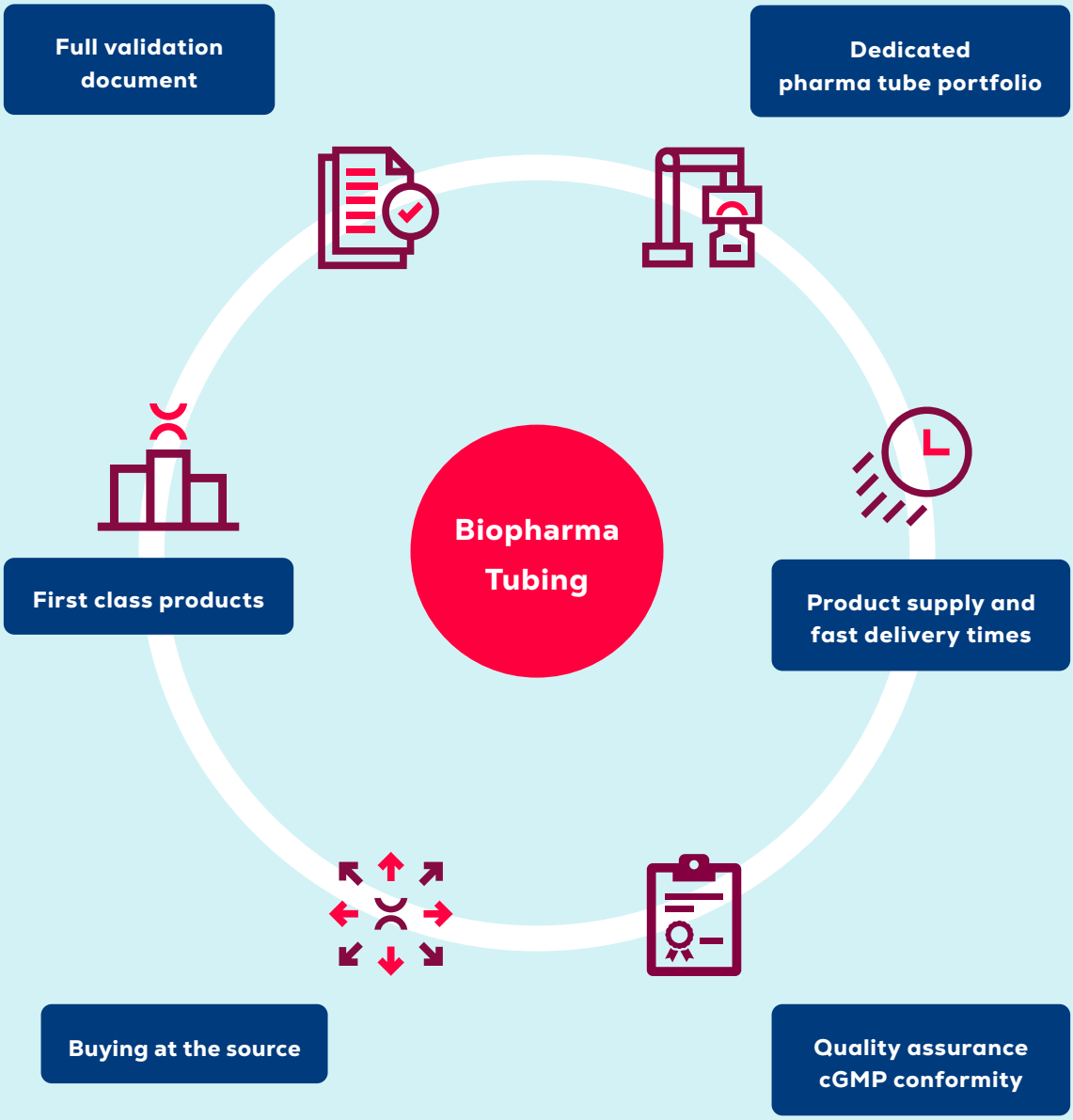
Phone: +49 6155-8981-400 Fax: +49 6155 8981-500
Safety Data Sheet Service: +49 6155 8981-522

Contact person : Katharina Rieker

KFT SDS EU 00

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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