

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

1.1 Product identifier

Trade name: **fib-tem® S**

Article number: 503-16

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

Application of the substance / the preparation

Kit component of in vitro diagnostic test for the examination of the blood coagulation system.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Tem Innovations GmbH
Martin-Kollar-Strasse 13-15
D-81829 Munich
Germany
Tel.: +49 (0)89 454295 0
Fax: +49 (0)89 454295 22

Further information obtainable from: support@tem-international.de

1.4 Emergency telephone number:

Toxicological Information Centre Munich +49 (0)89 19240 (english spoken, 24h/7d)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Xn; Harmful

R22: Harmful if swallowed.

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

2.2 Label elements

Labelling according to EU guidelines:

Code letter and hazard designation of product:



Xn Harmful

Hazard-determining components of labelling:

sodium azide

Risk phrases:

22 Harmful if swallowed.

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

22 Do not breathe dust.

37 Wear suitable gloves.

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2.3 Other hazards No further relevant information available.

Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT.

vPvB: According to current knowledge, the product contains no vPvB.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterization:

Description:

Kit (503-16-20) consists of 20x 503-16 and contains mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 9048-46-8 EINECS: 232-936-2	Albumins, blood serum ⚠ Acute Tox. 4, H302	25-50%
CAS: 10043-52-4 EINECS: 233-140-8 Index number: 017-013-00-2	calcium chloride ☒ Xi R36 ⚠ Eye Irrit. 2, H319	10-25%
CAS: 77-86-1 EINECS: 201-064-4	Tris(hydroxymethyl)-aminomethan ☒ Xi R36/37/38 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-10%
CAS: 26628-22-8 EINECS: 247-852-1 Index number: 011-004-00-7	sodium azide ☒ T+ R28; ☒ N R50/53 R32 ⚠ Acute Tox. 2, H300; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.1-1%

Additional information: For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation: Move individual to fresh air, seek medical advice in case of complaints.

After skin contact: Immediately rinse with water.

After eye contact: Flush immediately with plenty of water for 15 min.

After swallowing: Call for a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.**5.2 Special hazards arising from the substance or mixture** No further relevant information available.**5.3 Advice for firefighters****Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.**6.3 Methods and material for containment and cleaning up:**

Pick up mechanically.

Dispose contaminated material as waste according to item 13.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling Prevent formation of dust.**Information about fire - and explosion protection:** No special measures required.**7.2 Conditions for safe storage, including any incompatibilities****Storage****Requirements to be met by storerooms and receptacles:** No special requirements.**Information about storage in one common storage facility:** Not required.**Further information about storage conditions:**

Store between 2 - 8 °C.

Do not seal receptacle gas tight.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical facilities: No further data; see item 7.

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8.1 Control parameters**Ingredients with limit values that require monitoring at the workplace:****26628-22-8 sodium azide**

WEL (Great Britain)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ (as NaN ₃), Sk
MAK (Switzerland)	Short-term value: 0.4 e mg/m ³ Long-term value: 0.2 e mg/m ³
IOELV (EU)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ Skin

Additional information: The lists valid during the making were used as basis.**8.2 Exposure controls****Personal protective equipment:****General protective and hygienic measures:**

Prevent formation of dust.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.**Protection of hands:**

Protective gloves

Material of gloves Chemical resistant gloves.**Eye protection:**

Tightly sealed goggles

Limitation and supervision of exposure into the environment

Do not allow to enter sewers/ surface or ground water.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****General Information****Appearance:**

Form:	Powder
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

pH-value: 7.4 after dissolution in water.

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Change in condition	
<i>Melting point/Melting range:</i>	Not determined.
<i>Boiling point/Boiling range:</i>	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Product is not flammable.
Ignition temperature:	Not determined.
<i>Decomposition temperature:</i>	Not determined.
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
<i>Lower:</i>	Not determined.
<i>Upper:</i>	Not determined.
<i>Oxidizing properties</i>	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
<i>Relative density</i>	Not determined.
<i>Vapour density</i>	Not determined.
<i>Evaporation rate</i>	Not determined.
Solubility in / Miscibility with water:	Easily soluble.
Partition coefficient (n-octanol/water):	Not determined.
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability No decomposition if used according to specifications.

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: Avoid contact with strong acids.

10.6 Hazardous decomposition products:

Sodium azide develops very toxic gases upon contact with acids.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD/LC50 values relevant for classification:

26628-22-8 sodium azide

Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

Primary irritant effect:

on the skin: No irritating effect.

on the eye: No irritating effect.

Sensitization: No sensitizing effects known.

Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Harmful

Repeated dose toxicity No further relevant information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction) No CMR effects known.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Harmful to aquatic organisms.

12.2 Persistence and degradability Not easily biodegradable.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT.

vPvB: According to current knowledge, the product contains no vPvB.

12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation: Disposal must be made according to official regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

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SECTION 14: Transport information

14.1 UN-Number ADR, ADN, IMDG, IATA	Void
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Void
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA <i>Class</i>	Void
14.4 Packing group ADR, IMDG, IATA	Void
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
ADR <i>Remarks:</i>	Not classified
IMDG <i>Remarks:</i>	Not classified
IATA <i>Remarks:</i>	Not classified

SECTION 15: Regulatory information

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

National regulations:

Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous to water.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

The data and information given in this safety data sheet are based on the current state of our knowledge at the publishing date indicated in this safety data sheet. The safety data sheet shall give you indications for the safe handling, storage and use of the mentioned product, however the information included herein is not intended to be all-inclusive. The data and information can not be transferred to other products or other uses as the one declared in this safety data sheet. The data and information in this safety data sheet describe the safety requirements, but they do not represent any product specifications.

Relevant phrases

H300 Fatal if swallowed.
H302 Harmful if swallowed.

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- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- R28 Very toxic if swallowed.
- R32 Contact with acids liberates very toxic gas.
- R36 Irritating to eyes.
- R36/37/38 Irritating to eyes, respiratory system and skin.
- R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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