

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.08.2013

Revision: 15.08.2013

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

### 1.1 Product identifier

Trade name: **ex-tem® S****Article number:** 503-13

### 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.



Xi; Irritant

R36: Irritating to eyes.

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.

36 Irritating to eyes.

(Contd. on page 2)

# Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 15.08.2013

Trade name: **ex-tem® S**

(Contd. of page 1)

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

**Safety phrases:**

22 Do not breathe dust.

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

37 Wear suitable gloves.








**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 (503-13-20) consists of 20x 503-13 and contains mixture of substances listed below with nonhazardous additions.

**Dangerous components:**

CAS: 9048-46-8 EINECS: 232-936-2	Albumins, blood serum 	25-50%
CAS: 10043-52-4 EINECS: 233-140-8 Index number: 017-013-00-2	calcium chloride  	10-25%
CAS: 77-86-1 EINECS: 201-064-4	Tris(hydroxymethyl)-aminomethan  	5-10%
CAS: 26628-22-8 EINECS: 247-852-1 Index number: 011-004-00-7	sodium azide  R32 	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:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**After swallowing:** Call for a doctor immediately.**4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

(Contd. on page 3)

**Trade name: ex-tem<sup>®</sup> S**

(Contd. of page 2)

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

No further relevant information available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing agents:**CO<sub>2</sub>, 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 product to reach sewage system or any water course.**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.

Keep container tightly sealed.

**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.

(Contd. on page 4)

Trade name: **ex-tem® S**

(Contd. of page 3)

**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 <sup>3</sup> Long-term value: 0.1 mg/m <sup>3</sup> (as NaN <sub>3</sub> ), Sk
MAK (Switzerland)	Short-term value: 0.4 e mg/m <sup>3</sup> Long-term value: 0.2 e mg/m <sup>3</sup>
IOELV (EU)	Short-term value: 0.3 mg/m <sup>3</sup> Long-term value: 0.1 mg/m <sup>3</sup> 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.

(Contd. on page 5)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.08.2013

Revision: 15.08.2013

Trade name: **ex-tem® S**

(Contd. of page 4)

<b>Change in condition</b>	
<i>Melting point/Melting range:</i>	Not determined.
<i>Boiling point/Boiling range:</i>	Not applicable.
<b>Flash point:</b>	Not applicable.
<b>Flammability (solid, gaseous):</b>	Not determined.
<b>Ignition temperature:</b>	Not determined.
<i>Decomposition temperature:</i>	Not determined.
<b>Self-igniting:</b>	Product is not selfigniting.
<b>Danger of explosion:</b>	Product does not present an explosion hazard.
<b>Explosion limits:</b>	
<i>Lower:</i>	Not determined.
<i>Upper:</i>	Not determined.
<i>Oxidizing properties</i>	Not applicable.
<b>Vapour pressure:</b>	Not applicable.
<b>Density:</b>	Not determined.
<i>Relative density</i>	Not applicable.
<i>Vapour density</i>	Not applicable.
<i>Evaporation rate</i>	Not applicable.
<b>Solubility in / Miscibility with water:</b>	Easily soluble.
<b>Partition coefficient (n-octanol/water):</b>	Not applicable.
<b>Viscosity:</b>	
<i>Dynamic:</i>	Not applicable.
<i>Kinematic:</i>	Not applicable.
<b>9.2 Other information</b>	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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(Contd. on page 6)

Trade name: **ex-tem® S**

(Contd. of page 5)

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

**Acute toxicity** Harmful

#### 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:** 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

Irritant

**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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(Contd. on page 7)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.08.2013

Revision: 15.08.2013

Trade name: **ex-tem® S**

(Contd. of page 6)

## SECTION 14: Transport information

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

(Contd. on page 8)

**Safety data sheet**  
**according to 1907/2006/EC, Article 31**



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**Trade name: ex-tem® S**

(Contd. of page 7)

- H302 Harmful if swallowed.
- 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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