

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**Trade name: **in-tem® S***Article number:* 503-12**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

R68: Possible risk of irreversible effects.



Xi; Irritant

R36/38: Irritating to eyes and skin.

**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:**

phenol

**Risk phrases:**

36/38 Irritating to eyes and skin.

68 Possible risk of irreversible effects.

**Safety phrases:**

22 Do not breathe dust.

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26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
36/37 Wear suitable protective clothing and 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 (503-12-20) consists of 20x 503-12 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	10-25%
CAS: 108-95-2 EINECS: 203-632-7 Index number: 604-001-00-2	phenol ☠ T R23/24/25; ☠ C R34; ☠ Xn R48/20/21/22-68 Muta. Cat. 3 ⚠ Acute Tox. 3, H301; ⚠ Acute Tox. 3, H311; ⚠ Acute Tox. 3, H331; ⚠ Muta. 2, H341; ⚠ STOT RE 2, H373; ⚠ Skin Corr. 1B, H314	1-2.5%
CAS: 10043-52-4 EINECS: 233-140-8 Index number: 017-013-00-2	calcium chloride ☠ Xi R36 ⚠ Eye Irrit. 2, H319	1-2.5%
CAS: 10043-35-3 EINECS: 233-139-2 Index number: 005-007-00-2	boric acid ☠ T Repr. Cat. 2 R60-61 ⚠ Repr. 1B, H360	0.1-1%
CAS: 18917-91-4 EINECS: 242-670-9	aluminium trilactate ☠ Xi R36/37/38 ⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319; ⚠ STOT SE 3, H335	≤ 0.1%

**SVHC**

10043-35-3	boric acid
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**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:** No special measures required.

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

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:**

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

**After swallowing:** If symptoms persist consult doctor.

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

No further relevant information available.

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**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.

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**8.1 Control parameters**

<b>Ingredients with limit values that require monitoring at the workplace:</b>	
<b>108-95-2 phenol</b>	
WEL (Great Britain)	Short-term value: 16 mg/m <sup>3</sup> , 4 ppm Long-term value: 7.8 mg/m <sup>3</sup> , 2 ppm Sk
MAK (Switzerland)	Short-term value: 19 mg/m <sup>3</sup> , 5 ppm Long-term value: 19 mg/m <sup>3</sup> , 5 ppm H B M <sub>3</sub> ;
IOELV (EU)	Short-term value: 16 mg/m <sup>3</sup> , 4 ppm Long-term value: 8 mg/m <sup>3</sup> , 2 ppm Skin
<b>10043-35-3 boric acid</b>	
MAK (Switzerland)	Short-term value: 10 e mg/m <sup>3</sup> Long-term value: 10 e mg/m <sup>3</sup> SSb;
<b>18917-91-4 aluminium trilactate</b>	
MAK (Switzerland)	Long-term value: 2e mg/m <sup>3</sup>
<b>Ingredients with biological limit values:</b>	
<b>108-95-2 phenol</b>	
BAT (Switzerland)	250 mg/g Kreatinin Medium: U Sampling time: b Parameter: Phenol

**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:** Suitable respiratory protective device recommended.**Protection of hands:**

Protective gloves

**Eye protection:**

Tightly sealed goggles

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**Limitation and supervision of exposure into the environment**  
Do not allow product to reach sewage system or any water course.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

##### Appearance:

<i>Form:</i>	Powder
<i>Colour:</i>	According to product specification
<i>Odour:</i>	Characteristic
<i>Odour threshold:</i>	Not determined.

**pH-value:** 7.4 after dissolution in water.

#### Change in condition

<i>Melting point/Melting range:</i>	Not determined.
<i>Boiling point/Boiling range:</i>	Not applicable.

**Flash point:** Not applicable.

**Flammability (solid, gaseous):** Not determined.

**Ignition temperature:** Not determined.

**Decomposition temperature:** 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.

**Oxidizing properties:** Not applicable.

**Vapour pressure:** Not applicable.

**Density:** Not determined.

**Relative density:** Not applicable.

**Vapour density:** Not applicable.

**Evaporation rate:** Not applicable.

#### Solubility in / Miscibility with

**water:** Easily soluble.

**Partition coefficient (n-octanol/water):** Not applicable.

#### Viscosity:

<i>Dynamic:</i>	Not applicable.
<i>Kinematic:</i>	Not applicable.

**9.2 Other information** No further relevant information available.

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### 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:** No further relevant information available.

**10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

##### Acute toxicity

##### LD/LC50 values relevant for classification:

##### 108-95-2 phenol

Oral	LD50	317 mg/kg (rat)
Dermal	LD50	850 mg/kg (rabbit)

##### Primary irritant effect:

**on the skin:** Irritating to skin.

**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:

Irritant

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:** Based on the ingredients product is not classified as harmful for the environment.

**12.2 Persistence and degradability** No further relevant information available.

**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.

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**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.

## 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 Class	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>	
<b>ADR</b> <i>Remarks:</i>	Not classified
<b>IMDG</b> <i>Remarks:</i>	Not classified
<b>IATA</b> <i>Remarks:</i>	Not classified

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## SECTION 15: Regulatory information

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

**National regulations:**

**Information about limitation of use:**

Employment restrictions concerning pregnant and lactating women must be observed.

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

**Other regulations, limitations and prohibitive regulations**

**Substances of very high concern (SVHC) according to REACH, Article 57**

10043-35-3	boric acid
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**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**

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H360	May damage fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R34	Causes burns.
R36	Irritating to eyes.
R36/37/38	Irritating to eyes, respiratory system and skin.
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
R60	May impair fertility.
R61	May cause harm to the unborn child.
R68	Possible risk of irreversible effects.