



Material Safety Data Sheet

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1. Identification of the preparation.

THROMBOPLASTIN PT 4 (catalogue N° K-220)
THROMBOPLASTIN PT 10 (catalogue N° K-250)

THROMBOPLASTIN PT4/10 are designed for Health Service laboratories for the determination of prothrombin time (PT).

2. Hazards Identification.

The preparation is not regarded as dangerous.

3. Composition / information on components.

Dangerous components:	
sodium azide	Contains: < 0,1%
CAS number:	26628-22-8
EC number:	247-852-1;
Index number:	011-004-00-7 Harmfulness: T+; N; Phrases: R 28-32-50/53; S 28-45-60-61
Calcium chloride	Contains: < 0,18 %
CAS number:	10043-52-4
WE number:	233-140-8
Index number :	017-013-002 Harmfulness: Xi Phrases: R 36; S 2-22-24
Brij-35	Contains: < 0,08%
CAS number:	9002-92-0
EC number:	-----
Index number:	----- Harmfulness: Xi Phrases: R22-36; S 24
Polyethylene glycol	Contains: < 0,35%
CAS number	2532-68-3
WE number :	203-473-3
Index number:	603-027-00-1 Harmfulness: Xn; Phrases: R: 22; S: 2

Layer thickness: 0,11 mm
Breakthrough time: > 480 Min.

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Breakthrough time: > 480 Min.

Industrial hygiene: you must not have meals, drink, or smoke tobacco while working with the preparation, except in places designed for that purpose. Wash your hands after work with the substance carefully with soapy water. Apply skin-protective barrier cream.

9. Physical and Chemical Properties.

Form:	<i>solid</i>
Colour:	<i>white</i>
Odour:	<i>odorless</i>
Vapour pressure:	<i>no data available</i>
Boiling temperature:	<i>no data available</i>
Melting temperature:	<i>no data available</i>
Ignition temperature:	<i>no data available</i>
Flammability:	<i>no data available</i>
Density:	<i>no data available</i>
pH:	<i>no data available</i>

10. Stability and Reactivity:

Conditions that should be avoided:

Excessive heat may damage the material. Avoid prolonged exposure to direct sunlight.

Substances that should be avoided:

Strong oxidizing agents, strong acid and bases.

Dangerous decomposition products:

None

Further information:

A stabilized product.

11. Toxicological Information:

No data for the preparation. The preparation toxicity evaluation is based on evaluation of the toxicity of particular components.

Sodium azide:

Acute toxicity:

- LD₅₀ (oral, rat) – 27 mg/kg b. w.
- LD₅₀ (dermal, rabbit)- 20 mg/kg b. w.

Subacute to chronic toxicity:

No teratogenic effect in animal experiments.

Further toxicological information:

After inhalation of dusts/aerosols: Severe irritations of: mucous membranes, respiratory tract. Possible damages: pulmonary edema. Latency time until onset of action.

After skin contact: Slight irritations. Danger of skin absorption.

After eye contact: Slight irritations.

After swallowing: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

Systemic effects: CNS disorders, cardiovascular failure, tachycardia, drop in blood pressure, coughing, dyspnoea, spasms, headache, dizziness, nausea, vomiting, collapse, unconsciousness.

Further data:

The product should be handled with the care usual when dealing with chemicals.

12. Ecological Information:

No data for the preparation. The preparation toxicity evaluation is based on evaluation of the toxicity of particular components.

Sodium azide:

Ecotoxic effects:

Biological effects:

Highly toxic for aquatic organisms. May cause long-term adverse effects in the aquatic environment. Forms toxic mixtures in water, dilution measures notwithstanding. Herbicidal effect. Nematocidal effect.

Fish toxicity: *Limnea macrochirus* LC_{50} : 0,7 mg/l/96 h

Daphnia toxicity: *Daphnia pulex* EC_{50} : 4,2 mg/l /96 h

Algal toxicity: mixed culture of green algae IC_{50} : 272 mg/l

Bacterial toxicity: *Photobacterium phosphoreum* EC_{50} : 38,5 mg/l

Pseudomonas fluorescens UE_{50} : 2,6 mg/l

Further ecological data:

Do not allow for penetration into waters, sewage, or soil..

13. Disposal Considerations:

Product:

Chemical residues, in general, are included into special waste. Disposing of the latter is regulated by appropriate laws and ordinances. We recommend contacting the appropriate authorities, or waste disposal enterprises that will advise you on how to dispose of special waste.

Packing:

Remove in accordance with official regulations. Treat contaminated packages in the same way as the substance itself. If the regulations do not provide otherwise, non-contaminated packages can be treated like household waste or forward them to be utilized.

14. Transportation Information:

The product is not subject to transport regulations.

15. Regulatory Information:

Marking:

Not applicable.

Material Safety Data Sheet was prepared in accordance with:

The EC Directive Nr UE2001/58/WE, the EC Directive Nr 1999/45/EG, the EC Directive 67/548 EEC, EC Directive 88/379/EEC or the EC Directive 91/155/EEC (Dangerous Product Regulations incl. EC Guidelines). Regulation (EC) No 1907/2006 of European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (attachment II)
See Polish regulations.

16. Other Information.

These products are intended for in vitro diagnostic use only. Not for use in human. The foregoing information is based on the present state of our knowledge. It characterizes the product with respect to the appropriate safety measures. They do not guarantee the properties of the product.

We do not take responsibility for damage and losses that may result from inappropriate use of the preparation.

Reason of changes:

General updating

The foregoing safety chart prepared in electronic version is legally valid without sign manual.