



Material Safety Data Sheet

Manufacturer: PZ CORMAY S.A.
ul. Wiosenna 22
05-092 ŁOMIANKI
POLAND

phone/fax. (0-22) 751 79 10, 751 79 14

Date of card issue: 28.05.2009

I. Identification of the preparation.

FIBRINOGEN KIT-10 (catalogue N° K-500)

FIBRINOGEN KIT-10 is designed for Health Service laboratories for determination of fibrynogen concentration.

II. Kit contents

FIBRINOGEN KIT-10

- BOVINE THROMBIN 100 - the preparation is not regarded as dangerous.
- IMIDAZOLE BUFFER SALINE: Xn R 22-32-52/53 S 28-45-60-61
- HIGH FIBRINOGEN CONTROL - the preparation is not regarded as dangerous.
- LOW FIBRINOGEN CONTROL - - the preparation is not regarded as dangerous.



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1. Identification of the preparation.

FIBRINOGEN KIT-10 (catalogue N° K-500)

FIBRINOGEN KIT-10 is designed for Health Service laboratories for determination of fibrynogen concentration.

2. Hazards Identification.

The preparation is not regarded as dangerous.

3. Composition / information on components.

BOVINE THROMBIN 100	
Tris (Hydroxymethyl)-Aminomethane	Contains: < 1.89%
CAS number :	77-86-1
EC number:	201-064-4
Index number:	brak
Harmfulness:	Xi; Phrases: R 36/37/38; S - 26-36
Calcium chloride	Contains: < 0.198%
CAS number:	10043-52-4
EC number:	233-140-8
Index number :	017-013-002
Harmfulness:	Xi Phrases: R 36; S 2-22-24

4. First-Aid Measures.

After exposure by respiratory passages: fresh air, consult a doctor.

After skin contamination: wash off with large amount of water. Take off the contaminated clothing.

After contamination of eyes: rinse with large amount of water. In the event redness or itching seek medical advice.

After consumption: give the sufferer a large amount of water to drink.

If the sufferer feels unwell, consult a doctor.

5. Fire Fighting Measures:

Suitable extinguishing media: water, foam, powder, CO₂
Suitable for materials stored in immediate vicinity.
The preparation is not a flammable substance.

6. Accidental Release Measures:

Preventive measures related to the staff:
Avoid contamination with the preparation.
Cleaning /absorption procedures :
Collect small quantities with the use of an absorbing agent, rinse with large amount of water if necessary.

7. Handling and Storage:

Procedures:
In accordance with the norms generally accepted for chemicals in laboratories.
Storage:
Hermetically closed. In temperature from +2°C to +8°C.
Avoid freezing.

8. Exposure Controls/ Personal Protection:

Appropriate control parameter:
no data available
Personal control equipment:
Respiratory passages: not required
Eyes: required (protective glasses).
Hands: required (protective gloves).
Industrial hygiene:
Change contaminated clothing. Wash your hands after work with the substance.

9. Physical and Chemical Properties.

	<u>BOVINE THROMBIN 100</u>
Form:	liquid
Colour:	clear
Odour:	odorless
Vapour pressure:	no data available
Boiling temperature:	no data available
Melting temperature:	no data available
Ignition temperature:	no data available
Flammability:	no data available
Density:	no data available
pH:	no data available

10. Stability and Reactivity:

Conditions that should be avoided:
The preparation is stable in conditions provided by the manufacturer.
Substances that should be avoided:
No data available.
Dangerous decomposition products:
No dangerous decomposition products known.
Further information:
A stabilized product.

11. Toxicological Information:

Acute toxicity:

Quantitative data on the toxicity of this product are not available.

Further toxicological information:

Toxic activity should not be expected if you use this product appropriately.

Further data:

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

12. Ecological Information:

Ecotoxic activity:

Quantitative data on the ecological effect of this product are not available

Further ecological data:

Ecological problems should not be expected if you use and apply the product appropriately.

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.



Material Safety Data Sheet

Manufacturer PZ CORMAY S.A.
ul. Wiosenna 22
05-092 ŁOMIANKI
POLAND

phone/fax. (0-81) 749 44 34, 749 44 00

Date of card issue: 28.05.2009

1. Identification of the preparation.

FIBRINOGEN KIT-10 (catalogue N° K-500)

IMIDAZOLE BUFFERED SALINE kit are designed for use as supplementary reagent for determination of fibrinogen.

2. Hazards Identification.

Harmful: Harmful if swallowed.
Contact with acids liberates very toxic gas.
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

3. Composition / information on components.

Dangerous components:	
IMIDAZOLE BUFFER SALINE	
Sodium azide	Contains: < 0.35%
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
Imidazole	Contains: < 0.38%
CAS number:	288-32-4
EC number:	-
Index number :	- Harmfulness: Xi Phrases: R 22,34; S 26,36-37-39-45
Hydrogen chloride	Contains: < 0.19 %
CAS number:	7647-01-0
EC number:	231-595-7
Index number:	017-002-01-32(37) Harmfulness: Xi Phrases: R 36/37/38; S (1/2)9-26-36/37/39-45

9. Physical and Chemical Properties.

	<u>IMIDAZOLE BUFFER SALINE</u>
Form:	liquid
Colour:	clear
Odour:	odorless
Vapour pressure:	no data available
Boiling temperature:	no data available
Melting temperature:	no data available
Ignition temperature:	no data available
Flammability:	no data available
Density:	no data available
pH:	7.4

10. Stability and Reactivity:

Conditions that should be avoided:

The preparation is stable in conditions provided by the manufacturer.

Substances that should be avoided:

Heavy metals, metal salts, acids.

Dangerous decomposition products:

In the case of fire – nitrose gases,

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:



Harmful

It contains sodium azide.

Xn – Harmful

Risk phrases (R):

R 22-32-52/53 - Harmful if swallowed. Contact with acids liberates very toxic gas. Harmful to aquatic organisms, may cause long-term adverse effect in the aquatic environment.

Safety phrases (S):

S 28-45-60-61 – After contact with skin, wash immediately with plenty of water. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/ Safety data sheets.

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See Polish regulations.

16. Other Information.

R 22-32-52/53 - Harmful if swallowed. Contact with acids liberates very toxic
Gas. Harmful to aquatic organisms, may cause long-term adverse effect in the aquatic environment.

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2. Hazards Identification.

The preparation is not regarded as dangerous.

This serum has been tested for the HBsAg, HCV and HIV antibody and found to be non-reactive. However this material should be handled as though capable of transmitting infectious disease

3. Composition / information on components.

LOW FIBRINOGEN CONTROL
HIGH FIBRINOGEN CONTROL

Sodium hydroxide	Contains: < 0.12 %			
CAS number :	1310-73-2			
EC number :	215-185-5			
Index number:	011-002-00-6	Harmfulness: C	Phrases: R: 35;	S: (1/2)26-37/39,45

4. First-Aid Measures.

After exposure by respiratory passages: fresh air, consult a doctor.
After skin contamination: wash off with large amount of water. Take off the contaminated clothing.
After contamination of eyes: rinse with large amount of water. In the event redness or itching seek medical advice.
After consumption: give the sufferer a large amount of water to drink.
If the sufferer feels unwell, consult a doctor.

5.Fire Fighting Measures:

Suitable extinguishing media: water, foam, powder, CO₂
Suitable for materials stored in immediate vicinity.
The preparation is not a flammable substance.

6.Accidental Release Measures:

Preventive measures related to the staff:
Avoid contamination with the preparation.
Cleaning /absorption procedures :
Collect small quantities with the use of an absorbing agent, rinse with large amount of water if necessary.

7.Handling and Storage:

Procedures:
In accordance with the norms generally accepted for chemicals in laboratories.
Storage:
Hermetically closed. In temperature from +2°C to +8°C.

8.Exposure Controls/ Personal Protection:

Appropriate control parameter:
no data available
Personal control equipment:
Respiratory passages: not required
Eyes: required (protective glasses).
Hands: required (protective gloves).
Industrial hygiene:
Change contaminated clothing. Wash your hands after work with the substance.

9.Physical and Chemical Properties.

	<u>FIBRINOGEN CONTROL (LOW)/(HIGH)</u>
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:
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Substances that should be avoided:
No data available.
Dangerous decomposition products:
No dangerous decomposition products known.
Further information:
A stabilized product.

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Acute toxicity:

Quantitative data on the toxicity of this product are not available.

Further toxicological information:

Toxic activity should not be expected if you use this product appropriately.

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