



SAFETY DATA SHEET

According to
1907/2006/EC and amendment 453/2010/EC

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Trade name: Protein C ELISA
Product number: DE10901

1. IDENTIFICATION OF SUBSTANCE

REF / Article Number DE10901
Name of Product Protein C ELISA

Intended for professional use only

Manufacturer / Supplier

Demeditec Diagnostics GmbH
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2. HAZARD INFORMATION

2.1 Classification of the substances or mixture

Product is **not classified as hazardous** according to the European Regulation 1999/45/EC or 1272/2008/EC. Human health hazards No specific hazard.

2.2 Label Elements

Pictogram	None
Signal Word	None
Hazard Statement(s)	None
Precautionary Statement(s)	None
Supplement Hazard Statement(s)	None

2.3 Other Hazards


















None

3. COMPOSITION / DATA ON COMPONENTS

Coated microplate: Purified antigen coated onto polystyrene microwells.
Calibrators / Controls: Human antibodies < 1% in phosphate buffered saline with Tween 20 as detergent, sodium azide 0.09% as preservative and BSA for stabilization.
Enzyme conjugate: Peroxidase conjugated anti-human antibody < 0.0001% in phosphate buffered saline bovine serum albumin (BSA) for stabilization.
Sample buffer: Phosphate buffered saline with sodium azide 0.09% as preservative and BSA for stabilization.
Wash buffer: Tris buffered saline with Tween 20 as detergent and sodium azide 0.09% as preservative.
Substrate solution: Aqueous solution of TMB (3,3',5,5'-Tetramethylbenzidin) 0.04%. H₂O₂ <0.01% and ProClin 300 < 0.0001% as preservative.
Stop solution: Aqueous solution of hydrochloric acid 3 %.

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The bovine serum albumin was derived from bovine blood collected at USDA licensed establishment. Even though all mixtures do not meet the criteria for classification according to 1272/2008/EC we have summarized the components below for reason of completeness:

EINECS	CAS-No.	name	%	symbol	R-phrases / H-statements
Wash buffer					
247-852-1	26628-22-8	Sodium azide	<0.1	T+, N  	28-32-50/53 H300,H400,H410
201-064-4	77-86-1	Tris(hydroxymethyl)-aminomethan	<0.9	Xi 	36/38 H315, H319
Calibrators / Controls / Enzyme conjugate / Sample buffer					
247-852-1	26628-22-8	Sodium azide	<0.1	T+, N  	28-32-50/53 H300,H400,H410
Substrate					
259-364-6	54827-17-7	3,3',5,5'-Tetramethylbenzidine	<0.04	Xn  	20/21/22-36/37/38-40 H301,H311,H330,H341
247-500-7	26172-55-4	5-Chlor-2-methyl-4-isothiazolin-3-on	<0.01	T, N    	23/24/25-34-43-50/53, H272,H314,H317,H334
220-239-6	2682-20-4	2-Methyl-4-isothiazolin-3-on	<0.01	T,N    	23/24/25-34-43-50/53, H272,H314,H317,H334
231-765-0	7722-84-1	Hydrogen peroxide	<0.005	Xn,Xi  	22-41 H302,H318

The full text of R-phrases and H-statements is in article 16

4. FIRST AID MEASURES

4.1 Description of First Aid measures

General information: Consult a physician. Show this safety data sheet to the doctor in attendance.

After inhalation: If breathed in, move the concerned person into fresh air. In case of apnoea, give artificial respiration.

Consult a physician.

After skin contact: Wash off with plenty of water. Consult a physician.

After eye contact: Rinse the opened eye for several minutes with running water, if necessary remove contact lenses. Consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person.

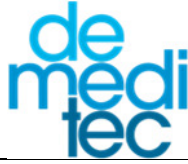
Rinse mouth with water, drink sufficient amount of water, consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

No data available



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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

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

The product itself is not inflammable; extinguishing measures should therefore be prepared for an environmental fire. In case of fire toxic vapors, e.g. nitric oxide, can be released.

5.3 Advice for fire fighters

Wear breath protective mask and protective clothes if necessary during firefighting.

6. ACCIDENTAL RELEASE MEASURE

Person-related safety precautions: Use personal protective equipment. Avoid breathing vapor/mist/gas. Care for appropriate ventilation.

Measures for environmental protection: Prevent seepage into sewage system, workpits and cellars. Do not allow to enter sewers/ surface or ground water.

Measures for cleaning/collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13.

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

7. HANDLING AND STORAGE

Handling: Special measures are not required.

Storage: Store at 2 to 8 °C. Protect from light.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION GEAR

Respiratory protection: Not required

Hand protection: Wear protective gloves of nitrile rubber or nature latex.

Eye protection: Wear protective glasses

9. PHYSICAL AND CHEMICAL PROPERTIES

Coated microplate: Polystyrol microwells in foil pouch.

Calibrators: Yellow fluid in polyethylene bottle.

Enzyme conjugate: Red (IgA), Blue (IgG), Green (IgM) fluid in polyethylene bottle.

Sample buffer: Yellow fluid in polyethylene bottle.

Wash buffer: Colorless fluid in polyethylene bottle.

Substrate solution: Colorless fluid in polyethylene bottle.

Stop solution: Colorless fluid in polyethylene bottle.



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10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available

10.2 Chemical stability

No data available

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the product)

10.5 Incompatible materials

Oxidizing agents, metals (will not cause a dangerous reaction, but destroys the quality of the product)

10.6 Hazardous decomposition products

Dangerous decomposition products are not known.

11. TOXICOLOGICAL INFORMATION

Used according to intended use no toxicological reactions known.

12. ECOLOGICAL INFORMATION

Used according to intended use no ecological reactions known.

13. DISPOSAL CONSIDERATIONS

Waste should be disposed of in accordance with federal, state and local environmental control regulations. When disposing of conjugate solution, sample buffer or wash buffer flush drains with copious amounts of water. Disposal of packaging according to the instructions of the public authorities.

14. TRANSPORT INFORMATION

This product is not subject to official transport regulations.

15. REGULATIONS

1907/2006/EC Registration, evaluation and authorization of chemicals regulation (REACH)
1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EWG and 1999/45/EC, amending 1907/2006/EC
453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

This product is not classified according to the EU regulations 1272/2008. No labeling requirement



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16. OTHER INFORMATION

Revision according to 453/2010 EU.

All mixtures do not meet the criteria for classification according to 1272/2008/EC.

Safety data for product including all components. This product is intended for professional laboratory use. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship

Full text to the R-Phrases mentioned in heading 3:

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

R22 Harmful if swallowed.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R28 Very toxic if swallowed

R32 Contact with acids liberates very toxic gas

R34 Causes burns.

R36/38 Irritating to eyes and skin.

R36/37/38 Irritating to eyes, respiratory system and skin.

R40 Possible risk of cancer.

R41 Risk of serious damage to eyes.

R43 May cause sensitization by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Full text to the H-statements mentioned in heading 3:

H272 May intensify fire; oxidizer. H300 Fatal if swallowed.

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.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage. H319 Causes serious eye irritation. H330 Fatal if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H341 Suspected of causing genetic defects. H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects.

The REACH registration numbers is not available as the substances or its use is exempted from registration according to article 2 REACH Regulation EC 1907/2006, or the annual tonnage does not require a registration and is envisaged for a later registration deadline.

Department issuing MSDS

Quality control

Date of issue: 29th January 2014