

Safety Data Sheet

according to Regulation (EC) No.1907/2006
released 2015/04/24



GENERAL SECTION

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers

Product name: OXYSTAT
COLORIMETRIC ASSAY FOR THE QUANTITATIVE
DETERMINATION OF PEROXIDES IN EDTA PLASMA, SERUM AND
OTHER BIOLOGICAL FLUIDS
Product Number: BI-5007, 12 X 8 TESTS
Brand: Biomedica Medizinprodukte GmbH & Co KG

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: IN-VITRO DIAGNOSTICS IN EU (CE-marked)

1.3. Details of the supplier of the data sheet

Company: Biomedica Medizinprodukte GmbH & Co KG, A-1210 Wien,
Divischgasse 4
Telephone: +43/1/291 07 45
Fax: +43/1/291 07 85
E-mail: export@bmgrp.com
Prepared by Biomedica Slovakia s.r.o., Bratislava, Drobneho 27

1.4. Emergency telephone number

Austrian Poison Control Center Phone: +43-1-4064343

1.5. Further information

All reagents sold by BIOMEDICA must be handled only by qualified laboratory personal.
All preservative substances used in our products are there in too low concentrations to constitute any danger and standard laboratory precautions should suffice for effective protection.

Nonetheless, in the case of unusual exposure, the form(s), furnished in the appendix, provoke(s) all the necessary information.

1.6. Partition of section 2-16 of the data safety sheet in specific forms

The following are hazardous substances present in this product:

Hazardous substance	Substance part of the following ELISA kit component, [Identification name of vial]	Quantity/ concentration of (hazardous) substance	Material Safety data sheet [no.]	Page of this MSDS
Substrate (TMB solution)	SOLC	0.1%	1	2
Stop Solution	STOP	9,81%	2	9
Controls, Calibrator	CTRL 1+2, CAL	100%	3	16

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SPECIFIC SECTION

Material safety data sheet no.1

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers

Kit component name: TMB substrate
component ID: SOLC
Brand: Biomedica Medizinprodukte GmbH & Co KG

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: AS SINGLE COMPONENT FOR RESEARCH USE ONLY

1.3. Details of the supplier of the data sheet

Company: Biomedica Medizinprodukte GmbH & Co KG, A-1210 Wien,
Divischgasse 4
Telephone: +43/1/291 07 45
Fax: +43/1/291 07 85
E-mail: export@bmgrp.com

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Although it is not classified as hazardous according to the European Regulation 1999/45/EC the product should be handled with the usual care for all chemicals, in order to avoid synergistic effects.

Because of the preservative it may be dangerous for water organisms.

2.2. Label elements

Labeling according Regulation (EC) No 1272/2008 [CLP]

Pictogram	none
Signal word	none
Hazard statement	none
Precautionary statement	none
Supplemental hazard statements	none

2.3. Other hazards

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

See section 3.2

3.2. Mixtures

Chemical characterization of product composition:

Aqueous solution of TMB, hydrogen peroxide, Tween 20 as detergent, citrate, EDTA, Kathon CG as preservative

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Dangerous components:

Component	Classification R-phrases	Percentage
3,3',5,5'-Tetramethylbenzidine		
EINECS: 259-364-6 CAS-NR: 54827-17-7	X _n R20/21/22-36/37/38-40	0.036%
Ethylene diamine tetraacetate disodium salt MW: C ₁₀ H ₁₄ O ₈ N ₂ Na ₂ ·2H ₂ O		
EINECS: 205-358-3 CAS-NR: 6381-92-6	Xi, R36/38 S26/37/39	0.093%
5-Chlor-2-methyl-4-isothiazolin-3-one		
EINECS: 247-500-7 CAS-NR: 26172-55-4	T, N R23/24/25-34-43-50/53	0.00009%
2-Methyl-4-isothiazolin-3-one		
EINECS: 220-239-6 CAS-NR: 2682-20-4	T, N R23/24/25-34-43-50/53	0.00003%
Hydrogen peroxide		
EINECS: 231-765-0 CAS-NR: 7722-84-1	C, O R8/34	0.002%

For the full text of the H-statements and R-phrases mentioned in this section, see section 16

4. FIRST AID MEASURES

4.1. Description of the first aid measures

General advice

Contaminated clothing should be washed prior to next use. Consult a physician, show this safety data sheet to the doctor in attendance.

In case of skin contact

After contact with skin carefully wash with water.

In case of eye contact

After contact with the eyes carefully rinse the opened eye with running water for several minutes and consult a physician.

If swallowed

After swallowing, rinse mouth and drink 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.

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

In case of fire toxic vapours can be released.

Wear breath protective mask and protective clothes if necessary during fire fighting.

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5.4. Further information

The product itself is not inflammable; extinguishing measures should therefore be prepared for an environmental fire.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with skin and eyes.

6.2. Environmental precautions

Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up

Dilute with plenty of water. Ventilate and clean affected area very carefully after having completely disposed off the material.

6.4. Reference to other sections

No data available.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Special measures are not required.

7.2. Conditions for safe storage, including any incompatibilities

At 2-8°C in closed HDPE or PP bottles. Protect from light.

7.3. Specific end uses

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Components with workplace parameters

EINECS	name	limit value according MAK (TRGS 900)
259-364-6	3,3',5,5'-Tetramethylbenzidine	not listed
205-358-3	Ethylene diamine tetraacetate disodium salt	not listed
247-500-7	5-Chlor-2-methyl-4-isothiazolin-3-one	0.05 mg/m ³
220-239-6	2-Methyl-4-isothiazolin-3-one	0.05 mg/m ³
231-765-0	Hydrogen peroxide	1.4 mg/m ³

By using the product according to the requirements, no air pollution is to be expected.

8.2. Expose controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3. Personal protective equipment

Respiratory protection: not required

Hand protection: protective gloves of nitril-rubber or natural latex

Eye protection: protective glasses. Tightly fitting safety goggles. Face-shield (8-inch minimum). Use equipment for eye protection tested

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and approved under appropriate government standards such
as NIOSH (US) or EN 166(EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

a) Appearance form:	liquid product, slightly foaming when shaken
b) Colour:	clear
c) Odour:	characteristic
d) pH:	3.6 – 3.8
e) Melting point/freezing point:	no data available.
f) Initial boiling point and boiling range:	100°C
g) Flash point:	not applicable
h) Evaporation rate:	no data available.
i) Flammability (solid, gas):	no data available.
j) Upper/lower flammability or explosive limits:	no data available.
k) Vapour pressure:	no data available.
l) Vapour density:	no data available.
m) Relative density:	1.003 g/ml
n) Water solubility:	complete soluble/miscible
o) Partition coefficient: n-octanol/water:	complete soluble/miscible in protic solvents
p) Auto-ignition temperature:	no data available.
q) Decomposition temperature:	no data available.
r) Viscosity:	no data available.
s) Explosive properties:	no data available.
t) Oxidizing properties:	no data available.

9.2. Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

Chemically stable under recommended conditions of use and storage.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Strong heat, light, especially sunlight will not cause a dangerous reaction, but destroys the quality as substrate solution.

10.5. Incompatible materials

Heavy metal salts, peroxidases and catalases will not cause a dangerous reaction, but destroys the quality as substrate solution.

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10.6. Hazardous decomposition products

The final decomposition product is the yellow Di-ammoniumion of Tetra-methylbenzidin, a slightly water soluble biodegradable substance not classified as hazardous.

Note: contains preservatives as stated under SPECIFIC SECTION material safety data sheet NO.1, point 3 *COMPOSITION/INFORMATION ON INGREDIENTS*.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Component	valuation	value	species
3,3',5,5'-tetramethylbenzidine	no information		
Ethylene diamine tetraacetate disodium salt	LD50 (oral)	2000 mg/kg	rat
5-chlor-2-methyl-4-isothiazolin-3-one	LD50 (oral)	3350 mg/kg	rat
2-methyl-4-isothiazolin-3-one	LD50 (oral)	550 mg/kg	rat
hydrogen peroxide	LD50 (oral)	1232 mg/kg	rat
	LD50 (dermal)	3000 mg/kg	rabbit

Further toxicological information:

Quantitative data concerning toxicity of the product do not exist.

12. ECOLOGICAL INFORMATION

Only relevant for the preservatives 5-chlor-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one

12.1. Toxicity

species	valuation	value
trout	LC50 (mg/l)	0.19
bass	LC50 (mg/l)	0.28
marine algae (Skeletonema costatum)	EC50 (mg/l)	0.003
algae (Selenastrum capricornutum)	EC50 (mg/l)	0.018
invertebrates (Daphnia magna)	EC50 (mg/l)	0.16

12.2. Persistence and degradability

substance	t ½ anerobic (h)
5-chlor-2-methyl-4-isothiazolin-3-one	4.8
2-methyl-4-isothiazolin-3-one	9.1

12.3. Bio-accumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

If used properly, no ecological problems are to be expected.

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13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

May not be discarded together with the normal waste.

Chemicals or remaining residues have to be treated as special waste and should be discarded according to the appropriate legislation. Information can be collected from the responsible public authorities.

Contaminated packaging

Disposal according to the instructions of the public authorities. Contaminated packages have to be treated like the substance itself. Packaging, that is not contaminated, can be recycled or treated like normal house garbage.

14. TRANSPORT INFORMATION

14.1. UN number

Non-regulated, non-hazardous for transport.

14.2. UN proper shipping name

Non-regulated, non-hazardous for transport.

14.3. Transport hazard class(es)

Non-regulated, non-hazardous for transport.

14.4. Packaging group

Non-regulated, non-hazardous for transport.

14.5. Environmental hazards

No data available.

14.6. Reportable Quantity (RQ)

No data available.

14.7. Emergency Telephone Number (during transport)

CHEMTREC: 1-800-424-9300 (US and Canada)

1-703-527-3887 (International shipments)

14.8. Special precautions for user

No data available.

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No.1907/2006.

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

Symbol: not applicable.

Designation: not applicable.

15.2. Chemical Safety assessment

Water endangering class 1 (self-classification): low potential of water endangering.

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16. OTHER INFORMATION

Text of H-code(s) and R-phrases(s) mentioned in Section 3

classification	Number	description
Xn		harmful
Xi		irritant
N		environmental hazard
T		toxic
C		corrosive
O		oxidizing
R	8	Contact with combustible material may cause fire.
	20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
	23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
	34	Causes burns.
	36/37/38	Irritating to eyes, respiratory system and skin.
	40	Possible risk of cancer.
	43	May cause sensitization by skin contact.
	50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S	26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	37	Wear suitable gloves.
	39	Wear eye/face protection.

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Biomedica Medizinprodukte GmbH & Co KG shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.

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SPECIFIC SECTION

Material safety data sheet no.2

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers

Kit component name: Sulfuric acid (H₂SO₄)
component ID: STOP
Brand: Biomedica Medizinprodukte GmbH & Co KG

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: AS SINGLE COMPONENT FOR RESEARCH USE ONLY

1.3. Details of the supplier of the data sheet

Company: Biomedica Medizinprodukte GmbH & Co KG, A-1210 Wien,
Divischgasse 4
Telephone: +43/1/291 07 45
Fax: +43/1/291 07 85
E-mail: export@bmgrp.com


2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

According to Regulation (EC) No. 1272/2008 and according to EC-directives 67/548/EEC or 1999/45/EC.

2.2. Label elements

Labeling according Regulation (EC) No 1272/2008 [CLP]

Hazard Pictogram	Signal word
	Warning

Hazard warnings:

- H 315: Causes skin irritation
- H 319: Causes severe eye irritation

Precautions:

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P301+P330+P331 If swallowed: Rinse mouth out, do not induce vomiting.
- P309 In case of exposure or if you feel unwell.
- P310 Call the POISONS INFORMATION CENTRE or a doctor immediately.
- P305+P351 IN CASE OF CONTACT WITH THE EYES: Rinse carefully with water for a few minutes. Remove any contact lenses if possible. Continue rinsing.

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2.3. Other hazards

No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

See section 3.2

3.2. Mixtures

Component	Classification	Percentage
Sulfuric acid		
CAS-No. 7664-93-9 EC-Nr. 231-639-5 INDEX-Nr. 016-020-00-8	Skin Corr.1B;STOT SE3; H314 C, R35 S26, S30, S45	9.81%
Water		
CAS-No. 7732-18-5 EC-No. 231-791-2	-	90.19%

For the full text of the H-statements and R-phrases mentioned in this section, see section 16.

4. FIRST AID MEASURES

4.1. Description of the first aid measures

General advice

Consult a physician, show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Consult a physician.

In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 min and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person.

Rinse mouth with 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.

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

No data available.

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5.3. Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4. Further information

No data available.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2. Environmental precautions

Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

No data available.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid inhalation of vapour or mist.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

7.3. Specific end uses

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Components with workplace parameters

No data available.

8.2. Expose controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3. Personal protective equipment

Eye/face protection

Tightly fitting safety goggles. Face-shield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body protection

Lab coat protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

a) Appearance form:	liquid
b) Odour:	no data available.
c) Odour Threshold:	no data available.
d) pH:	no data available.
e) Melting point/freezing point:	no data available.
f) Initial boiling point and boiling range:	no data available.
g) Flash point:	no data available.
h) Evapour ation rate:	no data available.
i) Flammability (solid, gas):	no data available.
j) Upper/lower flammability or explosive limits:	no data available.
k) Vapour pressure:	no data available.
l) Vapour density:	no data available.
m) Relative density:	no data available.
n) Water solubility:	no data available.
o) Partition coefficient: n-octanol/water:	no data available.
p) Auto-ignition temperature:	no data available.
q) Decomposition temperature:	no data available.
r) Viscosity:	no data available.
s) Explosive properties:	no data available.
t) Oxidizing properties:	no data available.

9.2. Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

Chemically stable under recommended conditions of use and storage.

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10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No data available.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

No data available.

Skin corrosion/irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory or skin sensitization

No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (Sulfuric acid)

Reproductive toxicity

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

Aspiration hazard

No data available.

Potential health effects

Inhalation

May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.

Ingestion

May be harmful if swallowed. Causes burns.

Skin

May be harmful if absorbed through skin. Causes skin burns.

Eyes

May be harmful in contact with eyes. Causes eye burns.

Additional information

No data available.

12. ECOLOGICAL INFORMATION

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

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12.3. Bio-accumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1. UN number

Non-regulated, non-hazardous for transport.

14.2. UN proper shipping name

Non-regulated, non-hazardous for transport.

14.3. Transport hazard class(es)

Non-regulated, non-hazardous for transport.

14.4. Packaging group

Non-regulated, non-hazardous for transport.

14.5. Environmental hazards

No data available.

14.6. Reportable Quantity (RQ)

No data available.

14.7. Emergency Telephone Number (during transport)

CHEMTREC: 1-800-424-9300 (US and Canada)

1-703-527-3887 (International shipments)

14.8. Special precautions for user

No data available.

15. REGULATORY INFORMATION

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

No data available.

15.2. Chemical safety assessment

No data available.

16. OTHER INFORMATION

Text of H-code(s) and R-phrases(s) mentioned in Section 3

Classification	Number	description
Skin Corr.	1B	Skin corrosion
STOT SE	3	Specific target organ toxicity - single exposure
C		Corrosive
H	314	Causes severe skin burns and eye damage
R	35	Causes severe burns
S	26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	30	Never add water to this product
	45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Biomedica Medizinprodukte GmbH & Co KG shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.

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SPECIFIC SECTION

Material safety data sheet no.3

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifiers

Kit component name: Control
Component ID: CTRL 1+2
Kit component name: Calibrator
Component ID: CAL
Brand: Biomedica Medizinprodukte GmbH & Co KG

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: AS SINGLE COMPONENT FOR RESEARCH USE ONLY

1.3. Details of the supplier of the data sheet

Company: Biomedica Medizinprodukte GmbH & Co KG, A-1210 Wien,
Divischgasse 4
Telephone: +43/1/291 07 45
Fax: +43/1/291 07 85
E-mail: export@bmgrp.com

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

2.2. Label elements

Labeling according Regulation (EC) No 1272/2008 [CLP]

The product does not need to be labeled in accordance with EC directives or respective national laws.

2.3. Other hazards

No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

See section 3.2

3.2. Mixtures

Aqueous solution of human serum with Aprotinin and Proclin 300,
Proclin 300 as preservative.
Aprotinin inhibits several serine proteases (prevents both intrinsic pathway of coagulation and fibrinolysis).

Component	Classification	Percentage
human serum		
-	-	100%

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4. FIRST AID MEASURES

4.1. Description of the first aid measures

General advice

Consult a physician, show this safety data sheet to the doctor in attendance.

If inhaled

Move to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

In case of skin contact

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.

In case of eye contact

In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

If swallowed

If swallowed, wash out mouth with water provided person is conscious. Call a physician immediately.

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.

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Suitable: Use extinguishing media appropriate to surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Nature of decomposition products not known.

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

5.4. Further information

No data available.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear self-contained breathing apparatus, rubber boots, and heavy rubber gloves.

6.2. Methods and materials for containment and cleaning up

Sweep up, place in a bag and store for waste disposal. Avoid raising dust. Wash spill site with 10% bleach and ventilate area after material pickup is complete.

6.3. Reference to other sections

No data available.

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7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid inhalation. Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure.

7.2. Conditions for safe storage, including any incompatibilities

Conditions of storage: Keep tightly closed. Store below -25°C after reconstitution.

7.3. Specific end uses

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Components with workplace parameters

No data available.

8.2. Expose controls

ENGINEERING CONTROLS:

Safety shower and eye bath. Mechanical exhaust required.

GENERAL HYGIENE MEASURES:

Wash thoroughly after handling.

8.3. Personal protective equipment:

Respiratory protection: Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator.

Hand protection: Compatible chemical-resistant gloves.

Eye protection: Chemical safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

a) Appearance form:	lyophilised
b) Colour:	clear - yellowish
c) Odour:	characteristic
d) pH:	no data available.
e) Melting point/freezing point:	no data available.
f) Initial boiling point and boiling range:	no data available.
g) Flash point:	no data available.
h) Evapour ation rate:	no data available.
i) Flammability (solid, gas):	no data available.
j) Upper/lower flammability or explosive limits:	no data available.
k) Vapour pressure:	no data available.
l) Vapour density:	no data available.
m) Relative density:	no data available.
n) Water solubility:	no data available.
o) Partition coefficient: n-octanol/water:	no data available.
p) Auto-ignition temperature:	no data available.
q) Decomposition temperature:	no data available.
r) Viscosity:	no data available.
s) Explosive properties:	no data available.
t) Oxidizing properties:	no data available.

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9.2. Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity

Hazardous polymerization: will not occur.

10.2. Chemical stability

Chemically stable under recommended conditions of use and storage.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Strong oxidizing agents

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Nature of decomposition products not known.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

No data available.

Skin corrosion/irritation

Skin contact: May cause skin irritation.

Skin absorption: May be harmful if absorbed through the skin.

Serious eye damage/eye irritation

May cause eye irritation.

Respiratory or skin sensitization

Material may be irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled.

Germ cell mutagenicity

No data available.

Carcinogenicity

No data available.

Reproductive toxicity

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

Aspiration hazard

No data available.

Additional information

May be harmful if swallowed.

12. ECOLOGICAL INFORMATION

12.1. Toxicity

No harmful effect at used concentration.

12.2. Persistence and degradability

No data available.

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12.3. Bio-accumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product

Contact a licensed professional waste disposal service to dispose of this material. Disposal should be made in accordance with existing disposal practices employed for infectious waste at your institution. Observe all federal, state, and local environmental regulations.

14. TRANSPORT INFORMATION

14.1. UN number

Non-regulated, non-hazardous for transport.

14.2. UN proper shipping name

Non-regulated, non-hazardous for transport.

14.3. Transport hazard class(es)

Non-regulated, non-hazardous for transport.

14.4. Packaging group

Non-regulated, non-hazardous for transport.

14.5. Environmental hazards

No data available.

14.6. Reportable Quantity (RQ)

No data available.

14.7. Emergency Telephone Number (during transport)

CHEMTREC: 1-800-424-9300 (US and Canada)
1-703-527-3887 (International shipments)

14.8. Special precautions for user

No data available.

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15. REGULATORY INFORMATION

CLASSIFICATION AND LABELING ACCORDING TO EU DIRECTIVES

INDICATION OF DANGER: B Biohazard.

Not hazardous according to Directive 67/548/EEC.

Caution: Substance not yet fully tested (EU).

COUNTRY SPECIFIC INFORMATION

Germany

WGK: 3

Self-Classification

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

No data available.

15.2. Chemical safety assessment

No data available.

16. OTHER INFORMATION

None.

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Biomedica Medizinprodukte GmbH & Co KG shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.