

Declaration Concerning the Content of Dangerous Substances in medac Products

Each component of our products listed in enclosure 1 are classified according to EC Directive 67/548/EC and 1999/45/EEC as well as to the German "Gefahrstoffverordnung" (ordinance on dangerous chemicals and preparations).

A Material Safety Data Sheet (MSDS) according to EC directive 91/155/EEC and to the German TRGS 220, respectively, had been generated for the kit components "Wash buffer" and "Sample diluent" as these components have been categorised as irritant.

None of the remaining components has to be regarded as dangerous with respect to the above mentioned regulations.

A Material Safety Data Sheet (MSDS) according to EC directive 91/155/EEC and to the German TRGS 220, respectively, had been generated for the kit component "Stop solution" as it contains more than 1% sulfuric acid.

The Material Safety Data Sheets are attached as enclosures 2 and 3.

When using the kit components the general safety precautions for laboratories are sufficient. The informations written in the package leaflet have to be followed.

Date of issue: 11.03..2005

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Enclosure 1**Classified medac-Products**

Kat.-Nr.	Test-Kit
110-PKS	CMV-IgM-ELA Test PKS medac
112-PKS	CMV-IgA-ELA Test PKS medac
115-PKS	CMV-IgG-ELA Test PKS medac
115-Q-PKS	CMV-IgG-ELISA PKS medac
116-PKS	CMV-IgG-ELISA PKS medac
135-PKS	Rubella-IgM-ELA Test PKS medac
136-PKS	Rubella-IgG-ELISA PKS medac
360	Mycoplasma pneumoniae-IgG-ELISA medac
361	Mycoplasma pneumoniae-IgA-ELISA medac
362	Mycoplasma pneumoniae-IgM-ELISA medac
430-TMB	Chlamydia pneumoniae-IgG-sELISA medac
430-PLUS	Chlamydia pneumoniae-IgG-ELISA <i>plus</i> medac
431-TMB	Chlamydia pneumoniae-IgA-sELISA medac
431 PLUS	Chlamydia pneumoniae-IgA-ELISA <i>plus</i> medac
432-TMB	Chlamydia pneumoniae-IgM-sELISA medac
435	cHSP60-IgG-ELISA medac
480-TMB	Chlamydien-IgG-rELISA medac
485-TMB	Chlamydien-IgM-rELISA medac
490-TMB	Chlamydien-IgA-rELISA medac
497-TMB	Chlamydia trachomatis-IgG-pELISA medac
497-PLUS	Chlamydia trachomatis-IgG-ELISA <i>plus</i> medac
498-TMB	Chlamydia trachomatis-IgA-pELISA medac
498-PLUS	Chlamydia trachomatis-IgA-ELISA <i>plus</i> medac
10018-A	HAMA-ELISA medac

Material Safety Data Sheet**According to 91/155 EEC**

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1 Identification of substance/preparation and of the company

- **Product details:**
- **Trade names: Wash buffer and Sample diluent:** **WB** and **BAC-DIL** and **VIR-DIL**, respectively
- **Article number:**
valid for the following kits: 110-PKS, 112-PKS, 115-PKS, 115-Q-PKS, 116-PKS, 135-PKS, 136-PKS, 360, 361, 362, 430-TMB, 431-TMB, 432-TMB, 430-PLUS, 431-PLUS, 435, 480-TMB, 485-TMB, 490-TMB, 497-TMB, 498-TMB, 497-PLUS, 498-PLUS, 10018-A
- **Application of the substance / the preparation**
Immunochemical reagent for detection/auxiliary reagent
- **Manufacturer/Distributor:**
medac
Gesellschaft für klinische Spezialpräparate mbH
Theaterstr. 6
D-22880 Wedel / Germany Tel.: ++49-4103-8006-0
- **Informing department:** Diagnostic Division
- **Emergency information:** Tel.: ++ 49 - 41 03 - 80 06 - 0

2 Composition/Data on components

- **Chemical characterization of preparation**
- **Description:**
Water based solution
- **Dangerous components:**
55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) <0.05%
T, N; R 23/24/25-34-43-50/53
- **Additional information:**
For the wording of the listed risk phrases refer to section 16.

3 Hazards identification

- **Hazard designation:** Xi Irritant
- **Information pertaining to particular dangers for man 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.
R 43 May cause sensitisation by skin contact.
- **Classification system:**
The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

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Trade names: Wash buffer and Sample diluent

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4 First aid measures

- **After inhalation:**
Supply fresh air and call for doctor for safety reasons.
In case of unconsciousness bring patient into stable side position for transport.
- **After skin contact:**
Instantly wash with water and soap and rinse thoroughly.
- **After eye contact:**
Rinse opened eye for several minutes under running water.
- **After swallowing:**
In case of persistent symptoms consult doctor.

5 Fire fighting measures

- **Suitable extinguishing agents:**
Product itself does not burn. Use fire fighting measures that suit the environment.
- **Protective equipment:**
No special measures required.

6 Accidental release measures

- **Person-related safety precautions:**
Prevent contact with skin and eyes.
- **Measures for environmental protection:**
Do not allow product to reach sewage system or water bodies.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

7 Handling and storage

- **Handling**
- **Information for safe handling:**
No special measures required.
- **Information about protection against explosions and fires:**
No special measures required.
- **Storage**
- **Requirements to be met by storerooms and containers:**
No special requirements.
- **Information about storage in one common storage facility:**
Not required.
- **Further information about storage conditions:**
None.

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Material Safety Data Sheet**According to 91/155 EEC**

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Trade names: Wash buffer and Sample diluent

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8 Exposure controls and personal protection

- **Additional information about design of technical systems:**
No further data; see item 7.
- **Components with critical values that require monitoring at the workplace:**
Not required according to German regulations.
- **Additional information:**
The official lists that were valid during the compilation were used as basis.
- **Personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures should be adhered to in handling the chemicals.
Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
- **Breathing equipment:**
Not required.
- **Protection of hands:**
Protective gloves.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves:**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material:**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**
Safety glasses

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Trade names: Wash buffer and Sample diluent

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9 Physical and chemical properties:

- **General Information**

- **Form:** Fluid
- **Colour:** Depending on the product, colourless or blue
- **Smell:** Nearly odourless
- **Change in condition**
- **Melting point/Melting range:** about 0°C
- **Boiling point/Boiling range:** about 100 ° C
- **Flash point:** Not applicable.
- **Self-inflammability:** Not self-inflammable.
- **Danger of explosion:** Not explosive.
- **Density at 20°C:** 1 g/cm³
- **Solubility in / Miscibility with**
- **Water:** fully miscible
- **pH-value: at 20°C:** 7.0-7.4
- **Solvent content:**
- **Organic solvents:** <0.5%

10 Stability and reactivity

- **Conditions to be avoided:**
No decomposition if used according to specifications.
- **Dangerous reactions:**
No dangerous reactions known.
- **Dangerous products of decomposition:**
No dangerous products of decomposition known.

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:**
No irritant effect known.
- **on the eye:**
No irritant effect known.
- **Sensitization:**
Sensitization possible by skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:
Irritant

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Material Safety Data Sheet**According to 91/155 EEC**

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Trade names: Wash buffer and Sample diluent

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12 Ecological information:**• General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water.

13 Disposal considerations**• Product:****• Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.

• Uncleaned packagings:**• Recommendation:**

Disposal must be made according to official regulations.

• Recommended cleaning agent:

Water, if necessary with cleaning agent.

14 Transport information**• Land transport ADR/RID and GGVS/GGVE (cross-border/domestic)****• ADR/RID-GGVS/E Class: -****• Maritime transport IMDG/GGVSea:****• Marine pollutant: No****15 Regulatory information****• Designation according to EC guidelines:**

The product has been classified and labelled in accordance with EC Directives / Ordinance on Hazardous Materials (GefStoffV, Germany).

• Code letter and hazard designation of product:

Xi Irritant

• Hazard-determining components of labelling:mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]
and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

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Trade names: Wash buffer and Sample diluent

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- **Risk phrases:**
43 May cause sensitisation by skin contact.

- **Safety phrases:**
24 Avoid contact with skin.
37 Wear suitable gloves.
60 This material and its container must be disposed of as hazardous waste.

- **National regulations:**

Class	Share in %
NK	0.5

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

16 Other information:

The above information and recommendations are believed to be correct as of the date of this Material Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. Medac shall not be held liable for any damage resulting from handling or from contact with the above product.

- **Relevant R-phrases:**
23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
34 Causes burns.
43 May cause sensitisation by skin contact.
50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **Department issuing data specification sheet:** Dept. for product safety

- **Replaces version from:** First version; date of issue: 11.03.2005.

Material Safety Data Sheet

According to 91/155 EEC

Reviewed on 11.03.2005

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1 Identification of substance/preparation and of the company:

- **Product details:**
- **Trade name: Stop solution:** STOP
- **Article number:**
valid for the following kits: 110-PKS, 112-PKS, 115-PKS, 115-Q-PKS, 116-PKS, 135-PKS, 136-PKS, 360, 361, 362, 430-TMB, 431-TMB, 432-TMB, 430-PLUS, 431-PLUS, 435, 480-TMB, 485-TMB, 490-TMB, 497-TMB, 498-TMB, 497-PLUS, 498-PLUS, 10018-A
- **Application of the substance / the preparation**
Immunochemical reagent for detection/auxiliary reagent
- **Manufacturer/Distributor:**
medac
Gesellschaft für klinische Spezialpräparate mbH
Theaterstr. 6
D-22880 Wedel / Germany Tel.: ++49-4103-8006-0
- **Informing department:** Diagnostic Division
- **Emergency information:** Tel.: ++ 49 - 41 03 - 80 06 - 0

2 Composition/Data on components:

- **Chemical characterization of preparation**
- **Description:**
Water based solution
- **Dangerous components:**
sulphuric acid 3-5 %
[CAS: 7664-93-9]
[EINECS: 231-639-5]
C; R 35
- **Additional information:**
For the wording of the listed risk phrases refer to section 16.

3 Hazards identification

- **Hazard designation:**
void
- **Information pertaining to particular dangers for man and environment:**
void

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Trade name: Stop solution

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4 First aid measures

- **General information:**
No special measures required.
- **After inhalation:**
Supply fresh air; consult doctor in case of symptoms.
- **After skin contact:**
Rinse well with water immediately.
- **After eye contact:**
Rinse opened eye for several minutes under running water.
- **After swallowing:**
Let drink much water.
In case of persistent symptoms consult doctor.

5 Fire fighting measures

- **Suitable extinguishing agents:**
Product itself does not burn. Use fire fighting measures that suit the environment.
- **Special hazards caused by the material, its products of combustion or flue gases:**
Sulphur dioxide (SO₂)
- **Protective equipment:**
In case of burning of a larger amount:
Wear full protective suit.
Wear self-contained breathing apparatus.

6 Accidental release measures

- **Person-related safety precautions:**
Do not inhale vapors.
- **Measures for environmental protection:**
Do not allow product to reach sewage system or water bodies.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Additional information:**
No dangerous materials are released.
Neutralisation possible with diluted sodium hydroxide solution (heat development!) or sodium carbonate or hydrogen carbonate (bubbles!).

7 Handling and storage

- **Handling**
- **Information for safe handling:** No special measures required.
- **Information about protection against explosions and fires:**
No special measures required.

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Trade name: Stop solution

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- **Storage**
- **Requirements to be met by storerooms and containers:**
No special requirements.
- **Information about storage in one common storage facility:**
Not required.
- **Further information about storage conditions:**
None.
- **Storage class:**
8 B (VCI)

8 Exposure controls and personal protection

- **Additional information about design of technical systems:**
No further data; see item 7.
- **Components with critical values that require monitoring at the workplace:**
7664-93-9 sulphuric acid
OES: Long-term value: 1 mg/m³
Additional information:
- The official lists that were valid during the compilation were used as basis.

- **Personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures should be adhered to in handling the chemicals.
Keep away from foodstuffs, beverages and food.
Wash hands during breaks and at the end of the work.
- **Breathing equipment:**
Not required.
- **Protection of hands:**
Not required.
- **Material of gloves:**
Not applicable.
- **Penetration time of glove material:**
Not applicable.
- **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are:**
Not applicable.
- **For the permanent contact gloves made of the following materials are suitable:**
Not applicable.
- **Eye protection:**
Safety glasses.

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Material Safety Data Sheet**According to 91/155 EEC**

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Trade name: Stop solution

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9 Physical and chemical properties:

- **General Information**
- **Form:** Fluid
- **Colour:** Colourless
- **Smell:** Odourless

- **Change in condition**
- **Melting point/Melting range:** Not determined.
- **Boiling point/Boiling range:** About 100 °C

- **Flash point:** Not applicable.
- **Self-inflammability:** Not self-inflammable.
- **Danger of explosion:** Not explosive.
- **Density at 20°C:** 1 g/cm³

- **Solubility in / Miscibility with**
- **Water:** fully miscible
- **pH-value: at 20°C:** <1
- **Solvent content:**
- **Organic solvents:** 0.0%

10 Stability and reactivity

- **Conditions to be avoided:**
No decomposition if used according to specifications.
- **Materials to be avoided:**
base metals (-> hydrogen formation, danger of explosion)
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:**
No dangerous products of decomposition known.

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect known.
- **on the eye:** Irritant effect.
- **Sensitization:** No sensitizing effect known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.

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Material Safety Data Sheet**According to 91/155 EEC**

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Trade name: Stop solution

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12 Ecological information:

- **Behaviour in environmental systems:**
- **Mobility and bioaccumulation potential:** Low bioaccumulation potential.
- **Ecotoxicological effects:**
- **Aquatic toxicity:**
Harmful effect due to pH shift.
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water.

13 Disposal considerations

- **Product:**
- **Recommendation**
Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.
- **Uncleaned packagings:**
- **Recommendation:**
Disposal must be made according to official regulations.
- **Recommended cleaning agent:** Water, if necessary with cleaning agent.

14 Transport information

- **Land transport ADR/RID and GGVS/GGVE (cross-border/domestic)**
- **ADR/RID-GGVS/E Class:** -
- **Transport/Additional information:**
Because of small volume no classification as dangerous goods according to above regulations.

15 Regulatory information

- **Designation according to EC guidelines:**
The product is not subject to identification regulations under EC Directives and the Ordinance on Hazardous Materials (GefStoffV). Observe the normal safety regulations when handling chemicals
- **National regulations**
- **Water hazard class:**
Water hazard class 1 (Self-assessment): slightly hazardous for water.

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Material Safety Data Sheet**According to 91/155 EEC**

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Trade name: Stop solution

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16 Other information:

The above information and recommendations are believed to be correct as of the date of this Material Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. Medac shall not be held liable for any damage resulting from handling or from contact with the above product.

- **Relevant R-phrases**

35 Causes severe burns.

- **Department issuing data specification sheet:** Dept. for product safety
- **Replaces version from:** 12.07.2002.