

杭州博拓生物科技股份有限公司 Hangzhou Biotest Biotech Co., Ltd.	文件编号 Document No.: MSDS-0052
MSDS for Chlamydia Rapid Test	第 1 页共 3 页 Page 1 of 3

MSDS for Chlamydia Rapid Test

I .1.Indentification of the product

Product Name: Chlamydia Rapid Test

Brand: RightSign®

I .2.Use of the preparation

The Chlamydia Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Chlamydia trachomatis in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection.

I .3.Company Indentification

Company: Hangzhou Biotest Biotech Co., Ltd.

Address: #17 Futai Road, Zhongtai Street , Yuhang District , Hangzhou-311121.

P.R.China. 311121

Tel: +86-571-89058016

Fax: +86-571-88633388

E-mail: info@biotests.com.cn

I .4.Emergency telephone No.

Emergency telephone: +86-571-89058016

II Information of Ingredients

Sodium Azide Concentration: = <0.02% (7.5ng/test)

CAS#: 26628-22-8

III Hazards Indentification

Sodium Azide is one of acute toxicity.

IV First aid measures

General Information: The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test.

First-aid personnel: The personnel must wear protective clothing and gloves etc.

After inhalation: N/A

After skin contact: Wash with soap and water for 10 minutes and rinse thoroughly.

After eye contact: N/A

After swallowing: N/A

V. Fire-fighting measures

Suitable extinguishing agents: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire-extinguishing methods suitable to surrounding conditions.

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Protective equipment: Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

Additional information: The device contains combustible materials.

VI Accidental release measure

Avoid release to the environment.

VII. 1. Handling

Keep out of reach of children.

Adhere to good Laboratory Practices(disposal gloves)

VII. 2. Storage

Store in a dry place at +2°C to +30°C

Avoid storage near to heat sources

Accessible only for authorized persons

VIII. Exposure controls/personal protection

Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Use disposal gloves. Wear Lab coat.

IX. Physical and chemical properties

Description: In vitro diagnostics medical device. Test impregnated with dried chemical / biochemical reagents.

Form: Solid reaction strip that could be placed into a plastic cassette depending on the format used.

Colour: White solid with red lines.

Odour: N/A

pH value: N/A

Melting point: N/A

Ignition temperature: N/A

Flash point: N/A

Explosion limits: N/A

Density: N/A

X. Stability and reactivity

1. The product is stable in accordance with the recommended storage conditions.
2. Conditions to be avoided: Strong heating, direct contact with flames.
3. Substances to be avoided: only use provided diluent for sample dilution

XI. Toxicological information

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After skin contact: Contact with the chemicals impregnated in the test strip may cause mild irritation.

XII. Ecological information

The device contains plastic and other components that are not readily degradable. The Chlamydia Rapid Test should be discarded in a proper biohazard container after testing.

XIII. Disposal considerations

Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

XIV. Transport information

N/A

XV. Regulatory information

Safety data sheet available for professional user on request.

This product does not require special labeling in accordance with the appropriate EC directives as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

SARA: 1. Section 355 (extremely hazardous substances): Sodium azide.

2. Section 313 (specific toxic chemical listings): Sodium azide.

XVI. Other information

For professional in vitro Diagnostic use only. Consult instructions for use.

To the best of our knowledge, the information contained herein is accurate. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

References:

1. REGULATION (EC) No 1907/2006
2. REGULATION (EC) No 1272/2008
3. IVDD 98/79/EC
4. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachomatis in Urine of Asymptomatic Men. J.Clinical Microbiology, 32,24-27, (1994).
5. Jaschek, G. et al Direct Detection of Chlamydia trachomatis in Urine Specimens from Symptomatic and Asymptomatic Men by Using a Rapid Polymerase Chain Reaction Assay. J. Clinical Microbiology, 31,1209- 1212, (1993).
6. Schachter, J Sexually transmitted Chlamydia trachomatis infection. Postgraduate Medicine, 72, 60-69, (1982).

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MSDS for Chlamydia Buffer 1

I.1. Identification of the product

Product Name: Chlamydia Buffer 1

Brand: RightSign®

I.2. Use of the preparation

The Chlamydia Buffer is a kind of lubricating fluid only be used with Chlamydia Rapid Test for the qualitative detection of Chlamydia trachomatis in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection.

I.3. Company Identification

Company: Hangzhou Biotest Biotech Co., Ltd.

Address: #17 Futai Road, Zhongtai Street, Yuhang District, Hangzhou-311121.

P.R.China.

Tel: +86-571-89058016

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E-mail: info@biotests.com.cn

I.4. Emergency telephone No.

Emergency telephone: +86-571-89058016

II Information of Ingredients

Name of Ingredients	Cas No. of Ingredients	Concentration of Ingredients
Cholic Acid sodium hydrate	73163-53-8	≈0.05g/L
Sodium Hydroxide	1310-73-2	≈6.0g/L

III Hazards Identification

Sodium Hydroxide is one of the corrosive substances.

IV First aid measures

First-aid personnel: The personnel must wear protective clothing and gloves etc.

After inhalation: N/A

After skin contact: 1. Flush with soap and water for at least 15 minutes and remove contaminated clothing.

2. Get medical aid immediately. Wash clothing before reuse.

After eye contact: Open the lid and rinse with water for 10 minutes. If the pain continues, inform the eye specialist for medical treatment as soon as possible.

After swallowing: 1. Drink water.
2. See the doctor

V. Fire-fighting measures

N/A

VI Accidental release measure

Person-related safety precautions: Isolate spillage and clean up immediately.

Measures for environmental protection: 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). Rinse off area with water.

VII. 1. Handling

Observe the general safety regulations when handling chemicals.

Adhere to good Laboratory Practices(disposal gloves)

Avoid contact with the eyes, skin and mucous membranes.

Keep out of reach of children.

VII. 2. Storage

Store in a dry place at +2°C to +30°C

Avoid storage near to heat sources

Accessible only for authorized persons

VIII. Exposure controls/personal protection

Adhere to good laboratory practices (GLP).

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Use disposal gloves. Wear Lab coat.

IX. Physical and chemical properties

Form: Liquid

Colour: Colourless

Odour: Odourless

pH value: 7.4±0.1

Melting point: Similar to water, approximately 0°C.

Boiling point: Similar to water, approximately 100°C.

Ignition temperature: N/A

Flash point: N/A

Explosion limits: N/A

Density: N/A

X. Stability and reactivity

1. The product is stable in accordance with the recommended storage conditions.

2. Conditions to be avoided: Strong heating, direct contact with flames.

3. Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas.

XI. Toxicological information

After skin contact: Irritating effect.

After eye contact: Irritating effect.

After ingestion: Irritation of the membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

XII. Ecological information

Ecotoxic Effects: Quantitative data on the toxic effects of this product are not available.

Aquatic toxicity: Harmful effect due to pH shift.

Persistence and Degradability: The organic components are biodegradable.

Mobility and bioaccumulation potential: Does not accumulate in organisms.

The Chlamydia Buffer should be discarded in a proper biohazard container after testing.

XIII. Disposal considerations

Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent.

XIV. Transport information

UN-Number: 1823 (Sodium Hydroxide)

Packaging group: III(Sodium Hydroxide)

XV. Regulatory information

Labelling according to EU guidelines:

Safety phrases:

2 Keep out of reach of children

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

46 If swallowed, seek medical advice immediately and show this container or label.

60 This material and its container must be disposed of as hazardous waste

XVI. Other information

For professional in vitro Diagnostic use only. Consult instructions for use.

To the best of our knowledge, the information contained herein is accurate. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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References:

1. REGULATION (EC) No 1907/2006
2. REGULATION (EC) No 1272/2008
3. IVDD 98/79/EC
4. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachomatis in Urine of Asymptomatic Men. J.Clinical Microbiology, 32,24-27, (1994).
5. Jaschek, G. et al Direct Detection of Chlamydia trachomatis in Urine Specimens from Symptomatic and Asymptomatic Men by Using a Rapid Polymerase Chain Reaction Assay. J. Clinical Microbiology, 31,1209- 1212, (1993).
6. Schachter, J Sexually transmitted Chlamydia trachomatis infection. Postgraduate Medicine, 72, 60-69, (1982).

MSDS for Chlamydia Buffer 2

I.1. Identification of the product

Product Name: Chlamydia Buffer 2

Brand: RightSign®

I.2. Use of the preparation

The Chlamydia Buffer is a kind of lubricating fluid only be used with Chlamydia Rapid Test for the qualitative detection of Chlamydia trachomatis in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection.

I.3. Company Identification

Company: Hangzhou Biotest Biotech Co., Ltd.

Address: #17 Futai Road, Zhongtai Street, Yuhang District, Hangzhou-311121.
P.R.China.

Tel: +86-571-89058016

Fax: +86-571-88633388

E-mail: info@biotests.com.cn

I.4. Emergency telephone No.

Emergency telephone: +86-571-89058016

II Information of Ingredients

Name of Ingredients	Cas No. of Ingredients	Concentration of Ingredients
MOPSO sodium salt	79803-73-9	≈37.0g/L
BSA	9048-46-8	≈25.0g/L
Chaps	75621-03-3	≈4.0g/L
Sodium Azide	26628-22-8	0.2mg/ml
Detergent 1307 S-9	N/A	≈0.4g/L
HCl	7647-01-0	≈0.2N

III Hazards Identification

MOPSO sodium salt is one of the irritant substances.

Sodium Azide is one of the acute toxicity.

HCl is one of the corrosive substances.

IV First aid measures

First-aid personnel: The personnel must wear protective clothing and gloves etc.

After inhalation: N/A

After skin contact: 1. Flush with soap and water for at least 15 minutes and remove contaminated clothing.

2. Get medical aid immediately. Wash clothing before reuse.

After eye contact: Open the lid and rinse with water for 10 minutes. If the pain continues, inform the eye specialist for medical treatment as soon as possible.

After swallowing: 1. Drink water.
2. See the doctor

V. Fire-fighting measures

N/A

VI Accidental release measure

Person-related safety precautions: Isolate spillage and clean up immediately.

Measures for environmental protection: 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). Rinse off area with water.

VII. 1. Handling

Observe the general safety regulations when handling chemicals.

Adhere to good Laboratory Practices(disposal gloves)

Avoid contact with the eyes, skin and mucous membranes.

Keep out of reach of children.

VII. 2. Storage

Store in a dry place at +2°C to +30°C

Avoid storage near to heat sources

Accessible only for authorized persons

VIII. Exposure controls/personal protection

Adhere to good laboratory practices (GLP).

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Use disposal gloves. Wear Lab coat.

IX. Physical and chemical properties

Form: Liquid

Colour: Colourless

Odour: Odourless

pH value: 7.4±0.1

Melting point: Similar to water, approximately 0°C.

Boiling point: Similar to water, approximately 100°C.

Ignition temperature: N/A

Flash point: N/A

Explosion limits: N/A

Density: N/A

X. Stability and reactivity

1. The product is stable in accordance with the recommended storage conditions.
2. Conditions to be avoided: Strong heating, direct contact with flames.
3. Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas.

XI. Toxicological information

After skin contact: Irritating effect.

After eye contact: Irritating effect.

After ingestion: Irritation of the membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

XII. Ecological information

Ecotoxic Effects: Quantitative data on the toxic effects of this product are not available.

Aquatic toxicity: Harmful effect due to pH shift.

Persistence and Degradability: The organic components are biodegradable.

Mobility and bioaccumulation potential: Does not accumulate in organisms.

The Chlamydia Buffer should be discarded in a proper biohazard container after testing.

XIII. Disposal considerations

Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent.

XIV. Transport information

UN-Number: 1687(Sodium Azide)

1789 (HCl)

Packaging group: II(Sodium Azide)

II(HCl)

XV. Regulatory information

Labelling according to EU guidelines:

Safety phrases:

2 Keep out of reach of children

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

46 If swallowed, seek medical advice immediately and show this container or label.

60 This material and its container must be disposed of as hazardous waste

XVI. Other information

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To the best of our knowledge, the information contained herein is accurate. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

References:

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6. Schachter, J Sexually transmitted Chlamydia trachomatis infection. Postgraduate Medicine, 72, 60-69, (1982).