

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**  
Trade name NEPHROCHECK® Test Buffer Solution
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**  
Identified use(s) *In vitro diagnostic reagent.* For professional use only.
- 1.3 Details of the supplier of the safety data sheet**  
Company Identification Astute Medical, Inc.  
3550 General Atomics Ct.  
Building 2  
San Diego, CA 92121 USA  
Telephone +1 (858) 500-7000  
E-Mail (competent person) info@astutemedical.com
- 1.4 Emergency telephone number**  
Emergency Phone No. +1(855) 807-2783

## ▶ SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
- Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous.
- OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS Not classified as hazardous.
- 2.2 Label elements** No measures required.
- 2.3 Other hazards** None.

## ▶ SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**  
Description: *In vitro diagnostic reagent.* Aqueous solution.
- Dangerous components  
EC Classification No. 1272/2008

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard statement(s)	%W/W
Sodium azide*	26628-22-8	247-852-1	Not available	Acute Tox. 2; H300 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	< 0.1

- 3.3 Additional Information** For full text of H phrases see section 16.  
\* Substance with a community exposure limit.

## SECTION 4: FIRST AID MEASURES



- 4.1 Description of first aid measures**

Inhalation	Supply fresh air; consult doctor in case of complaint.
Skin Contact	Wash skin with soap and water.
Eye Contact	Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion	Wash out mouth with water. Consult a doctor in case of complaint.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	None known.
<b>4.3 Indication of the immediate medical attention and special treatment needed</b>	None.

## SECTION 5: FIRE-FIGHTING MEASURES

<b>5.1 Extinguishing media</b> Suitable Extinguishing Media	CO <sub>2</sub> , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
<b>5.2 Special hazards arising from the substance or mixture</b>	In case of fire, the following can be released: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ).
<b>5.3 Advice for fire-fighters</b>	Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage.
<b>6.2 Environmental precautions</b>	Do not allow the undiluted product to enter sewers/surface or ground water.
<b>6.3 Methods and material for containment and cleaning up</b>	Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to Section 13. Rinse off area with water.
<b>6.4 Reference to other sections</b>	8, 13

## SECTION 7: HANDLING AND STORAGE


<b>7.1 Precautions for safe handling</b>	Avoid contact with skin and eyes. Keep out of reach of children. Wash hands before breaks and after work.
<b>7.2 Conditions for safe storage, including any incompatibilities</b>	Store in the original container at 4 to 25°C.
<b>7.3 Specific end use(s)</b>	Use as per instructions for use.

## ► SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters**  
**8.1 Occupational Exposure Limits**  
**.1**

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m <sup>3</sup> )	STEL (ppm)	STEL (mg/m <sup>3</sup> )	Note:
Sodium azide As NaN <sub>3</sub>	26628-22-8		0.1		0.3	Sk EU IOELV / UK EH40
				0.11 (HN <sub>3</sub> )	0.29 (NaN <sub>3</sub> )	ACGIH TLV

Sk - Can be absorbed through skin.

<b>8.2</b>	<b>Exposure controls</b>	
<b>8.2.1</b>	<b>Appropriate engineering controls</b>	Not relevant for this material.
<b>8.2.2</b>	<b>Personal protection equipment</b>	
	Eye/face protection	Safety glasses recommended.
		
	Hand protection	Disposable gloves.
		
	Material of gloves:	Latex / natural rubber, Nitrile rubber
	Penetration time of glove material:	Gloves resistance is not critical when the product is handled according to the instructions for use.
	Body protection	Laboratory coat.
	Respiratory protection	Not normally required.
<b>8.2.3</b>	<b>Environmental Exposure Controls</b>	No special measures are required.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance	Clear liquid.
Colour	Colourless.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	8.5.
Melting Point (°C) / Freezing Point (°C)	Similar to water, approximately 0°C.
Boiling point/boiling range (°C):	Similar to water, approximately 100°C.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not determined.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (Pascal)	Similar to water, approximately 23 hPa.
Vapour Density (Air=1)	Not determined.
Density (g/ml)	~1.
Solubility (Water)	Soluble.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not determined.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising

### 9.2 Other information

Not available

## SECTION 10: STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	None known.
<b>10.2 Chemical stability</b>	The product is stable in accordance with the recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
<b>10.4 Conditions to avoid</b>	None
<b>10.5 Incompatible materials</b>	Strong acids, strong bases, strong oxidizing agents.
<b>10.6 Hazardous Decomposition Product(s)</b>	None known.

## ▶ SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### 11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

#### Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

### 11.2 Other information

Not applicable.

## SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	No data.
12.3 Bioaccumulative potential	No data.
12.4 Mobility in soil	No data.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	Not applicable.

## SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue:	18 01 07.
Packaging:	Disposal should be in accordance with local, state or national legislation. Packaging materials may be recycled. Contact your local service providers for further information.

## SECTION 14: TRANSPORT INFORMATION

14.1	<b>UN number</b>	Not applicable.
14.2	<b>UN Proper Shipping Name</b>	Not applicable.
14.3	<b>Transport hazard class(es)</b>	Not classified as dangerous for transport.
14.4	<b>Packing Group</b>	Not applicable.
14.5	<b>Environmental hazards</b>	Not applicable.
14.6	<b>Special precautions for user</b>	Not applicable.
14.7	<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## ▶ SECTION 15: REGULATORY INFORMATION

15.1	<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	<b>Carcinogen listings</b>	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA:	None of the ingredients is listed.
	<b>Californian Proposition 65</b>	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	<b>SARA</b>	
	Section 355 (extremely hazardous substances):	Sodium azide.
	Section 313 (specific toxic chemical listings):	Sodium azide.
15.2	<b>Chemical Safety Assessment</b>	Not applicable.

## ▶ SECTION 16: OTHER INFORMATION

### LEGEND

STOT	Specific Target Organ Toxicity
STEL	Short Term Exposure Limit
LTEL	Long Term Exposure limit
TWA	Time Weighted Average

### Classification code(s):

Acute Tox. 1	Acute toxicity, Category 1
Acute Tox. 2	Acute toxicity, Category 2
STOT RE 2	Specific Target Organ Toxicity, repeat exposure, Category 2
Aquatic Acute 1	Hazardous to the aquatic environment, Acute, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, Chronic, Category 1

### Hazard statement(s)

H300: Fatal if swallowed.  
H310: Fatal in contact with skin.  
H373: May cause damage to organs through prolonged or repeated exposure.  
H400: Very toxic to aquatic life.  
H410: Very toxic to aquatic life with long lasting effects.  
EUH032: Contact with acids liberates very toxic gas.

**References:**

Raw material safety data sheets.

**Additional Information**

Reason for update:

SECTION 2: SECTION 3: SECTION 8: SECTION 11:  
SECTION 15: SECTION 16:  
▶ Indicates altered section

Supersedes:

PN: 300130 Rev D

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. 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.

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

<b>1.1 Product identifier</b>	Trade name	NEPHROCHECK® Test Conjugate
<b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b>	Identified use(s)	<i>In vitro diagnostic reagent.</i> For professional use only.
<b>1.3 Details of the supplier of the safety data sheet</b>	Company Identification	Astute Medical, Inc. 3550 General Atomics Ct. Building 2 San Diego, CA 92121 USA
	Telephone	+1 (858) 500-7000
	E-Mail (competent person)	info@astutemedical.com
<b>1.4 Emergency telephone number</b>	Emergency Phone No.	+1(855) 807-2783

## ▶ SECTION 2: HAZARDS IDENTIFICATION

<b>2.1 Classification of the substance or mixture</b>	Regulation (EC) No. 1272/2008 (CLP)	Not classified as hazardous.
	OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS	Not classified as hazardous.
<b>2.2 Label elements</b>		No measures required.
<b>2.3 Other hazards</b>		None.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>3.2 Mixtures</b>	Description:	<i>In vitro diagnostic reagent.</i> Lyophilised mixture.
	Dangerous components:	The product does not contain reportable quantities of dangerous components.
	Additional information	None.

## SECTION 4: FIRST AID MEASURES



<b>4.1 Description of first aid measures</b>	Inhalation	Supply fresh air; consult doctor in case of complaint.
	Skin Contact	Wash skin with soap and water.
	Eye Contact	Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
	Ingestion	Wash out mouth with water. Consult a doctor in case of complaint.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>		None known.
<b>4.3 Indication of the immediate medical attention and special treatment needed</b>		None.

## SECTION 5: FIRE-FIGHTING MEASURES

- |  |                              |   |
|--|------------------------------|---|
| <b>5.1 Extinguishing media</b>                                   | Suitable Extinguishing Media | CO <sub>2</sub> , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.   |
| <b>5.2 Special hazards arising from the substance or mixture</b> |                              | In case of fire, the following can be released: Carbon oxides (CO <sub>x</sub> ).   |
| <b>5.3 Advice for fire-fighters</b>                              |                              | Use fire-extinguishing methods suitable to surrounding conditions.<br>Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires. |



## SECTION 6: ACCIDENTAL RELEASE MEASURES

- |  |  |  |
|--|--|--|
| <b>6.1 Personal precautions, protective equipment and emergency procedures</b> |  | Isolate spillage and clean up immediately.<br>Refer to Section 8 for protective measures when handling the spillage. |
| <b>6.2 Environmental precautions</b>   |  | No special requirements.   |
| <b>6.3 Methods and material for containment and cleaning up</b>                |  | Collect material and dispose of as waste according to Section 13.  |
| <b>6.4 Reference to other sections</b>   |  | Rinse off area with water.<br>8, 13  |

## ▶ SECTION 7: HANDLING AND STORAGE

- |   |  |   |
|---|--|---|
| <b>7.1 Precautions for safe handling</b>                                |  | Avoid contact with skin and eyes.<br>Keep out of reach of children.<br>Wash hands before breaks and after work.<br>Specimens should be handled as potentially infectious materials.<br>Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.<br>Clean work areas with hypochlorite or other disinfecting agent. |
| <b>7.2 Conditions for safe storage, including any incompatibilities</b> |  | Store in the original container at 4 to 25°C.   |
| <b>7.3 Specific end use(s)</b>  |  | Use as per instructions for use.  |

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- |   |   |  |
|---|---|--|
| <b>8.1 Control parameters</b>                 |   |  |
| <b>8.1.1 Occupational Exposure Limits</b>     |   | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| <b>8.2 Exposure controls</b>                  |   |  |
| <b>8.2.1 Appropriate engineering controls</b> |   | Not relevant for this material.  |
| <b>8.2.2 Personal protection equipment</b>    |   |  |
|   | Eye/face protection   | Safety glasses recommended.  |
|   |  |  |
|   | Hand protection   | Disposable gloves.   |
|   |  |  |
|   | Material of gloves:   | Latex / natural rubber, Nitrile rubber   |
|   | Penetration time of glove material:   | Gloves resistance is not critical when the product is handled according to the instructions for use.                               |



Body protection	Laboratory coat.
Respiratory protection	Not normally required.

**8.2.3 Environmental Exposure Controls** No special measures are required.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance	Solid.
Colour	White/Bluish.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not applicable.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (Pascal)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not determined.
Solubility (Water)	Soluble.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising

### 9.2 Other information

Not available

## SECTION 10: STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	None known.
<b>10.2 Chemical stability</b>	The product is stable in accordance with the recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	None known. Hazardous polymerisation will not occur.
<b>10.4 Conditions to avoid</b>	None
<b>10.5 Incompatible materials</b>	None known.
<b>10.6 Hazardous Decomposition Product(s)</b>	None known.

## ▶ SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### 11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are

STOT-single exposure	not met. Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

**Health Effects and Symptoms**

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

**11.2 Other information** Not applicable.

**SECTION 12: ECOLOGICAL INFORMATION**

<b>12.1 Toxicity</b>	The product does not contain significant quantities of ingredients that are environmentally toxic.
<b>12.2 Persistence and degradability</b>	No data.
<b>12.3 Bioaccumulative potential</b>	No data.
<b>12.4 Mobility in soil</b>	No data.
<b>12.5 Results of PBT and vPvB assessment</b>	Not applicable.
<b>12.6 Other adverse effects</b>	Not applicable.

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<b>Product:</b>	Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<b>European waste catalogue:</b>	18 01 03.
<b>Packaging:</b>	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

**SECTION 14: TRANSPORT INFORMATION**

<b>14.1 UN number</b>	Not applicable.
<b>14.2 UN Proper Shipping Name</b>	Not applicable.
<b>14.3 Transport hazard class(es)</b>	Not classified as dangerous for transport.
<b>14.4 Packing Group</b>	Not applicable.
<b>14.5 Environmental hazards</b>	Not applicable.
<b>14.6 Special precautions for user</b>	Not applicable.
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

**▶ SECTION 15: REGULATORY INFORMATION**

<b>15.1 Safety, health and environmental regulations/legislation specific for the</b>	In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200
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According to Regulation (EC) No. 1907/2006 (REACH), Annex II

**substance or mixture**

Consumer Product Safety Regulations 16 CFR 1600  
IVD Product Labelling 21 CFR 809

**Carcinogen listings**

IARC:

None of the ingredients is listed.

NTP:

None of the ingredients is listed.

ACGIH:

None of the ingredients is listed.

OSHA:

None of the ingredients is listed.

EPA:

None of the ingredients is listed.

**Californian Proposition 65**

Chemicals known to cause cancer:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity:

None of the ingredients is listed.

**SARA**

Section 355 (extremely hazardous substances):

None of the ingredients is listed.

Section 313 (specific toxic chemical listings):

None of the ingredients is listed.

**15.2 Chemical Safety Assessment**

Not applicable.

## SECTION 16: OTHER INFORMATION

**LEGEND**

STOT Specific Target Organ Toxicity

**References:**

Raw material safety data sheets.

**Additional Information**

Reason for update:

SECTION 2: SECTION 7: SECTION 11: SECTION 15:

► Indicates altered section

Supersedes:

PN: 300130 Rev D

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. 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.

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

<b>1.1 Product identifier</b>	Trade name	NEPHROCHECK® Test Cartridge
<b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b>	Identified use(s)	<i>In vitro</i> diagnostic medical device. For professional use only.
<b>1.3 Details of the supplier of the safety data sheet</b>	Company Identification	Astute Medical, Inc. 3550 General Atomics Ct. Building 2 San Diego, CA 92121 USA
	Telephone	+1 (858) 500-7000
	E-Mail (competent person)	info@astutemedical.com
<b>1.4 Emergency telephone number</b>	Emergency Phone No.	+1(855) 807-2783

## ► SECTION 2: HAZARDS IDENTIFICATION

<b>2.1 Classification of the substance or mixture Regulation (EC) No. 1272/2008 (CLP)</b>	Not classified as hazardous.
<b>OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS</b>	Not classified as hazardous.
<b>2.2 Label elements</b>	No measures required.
<b>2.3 Other hazards</b>	None.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>3.2 Mixtures</b>	Description:	<i>In vitro</i> diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagents.
	Dangerous components:	The product does not contain reportable quantities of dangerous components.
	Additional information	None.

## ► SECTION 4: FIRST AID MEASURES



<b>4.1 Description of first aid measures</b>	Inhalation	Not relevant for this material.
	Skin Contact	Wash skin with soap and water.
	Eye Contact	Not relevant for this material.
	Ingestion	Not relevant for this material.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>		None known.
<b>4.3 Indication of the immediate medical attention and special treatment needed</b>		None.

## SECTION 5: FIRE-FIGHTING MEASURES

- |  |   |
|--|---|
| <b>5.1 Extinguishing media</b><br>Suitable Extinguishing Media   | CO <sub>2</sub> , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.   |
| <b>5.2 Special hazards arising from the substance or mixture</b> | In case of fire, the following can be released: Carbon oxides (CO <sub>x</sub> ), Hazardous fumes.  |
| <b>5.3 Advice for fire-fighters</b>                              | Use fire-extinguishing methods suitable to surrounding conditions.<br>Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires. |



## ▶ SECTION 6: ACCIDENTAL RELEASE MEASURES

- |  |   |
|--|---|
| <b>6.1 Personal precautions, protective equipment and emergency procedures</b> | No special requirements.  |
| <b>6.2 Environmental precautions</b>   | No special requirements.  |
| <b>6.3 Methods and material for containment and cleaning up</b>                | Collect material and dispose of as waste according to Section 13. |
| <b>6.4 Reference to other sections</b>   | 8, 13   |

## ▶ SECTION 7: HANDLING AND STORAGE

- |   |  |
|---|--|
| <b>7.1 Precautions for safe handling</b>                                | Avoid contact with skin and eyes.<br>Keep out of reach of children.<br>Wash hands before breaks and after work.<br>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.<br>Clean work areas with hypochlorite or other disinfecting agent. |
| <b>7.2 Conditions for safe storage, including any incompatibilities</b> | Store in the original container at 4 to 25°C.  |
| <b>7.3 Specific end use(s)</b>  | Use as per instructions for use.   |

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- |   |  |
|---|--|
| <b>8.1 Control parameters</b>   |  |
| <b>8.1.1 Occupational Exposure Limits</b>   | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| <b>8.2 Exposure controls</b>  |  |
| <b>8.2.1 Appropriate engineering controls</b>                                       | Not relevant for this material.  |
| <b>8.2.2 Personal protection equipment</b>  |  |
| Eye/face protection   | Safety glasses recommended.  |
|  |  |
| Hand protection   | Disposable gloves.   |
|  |  |
| Material of gloves:   | Latex / natural rubber, Nitrile rubber   |
| Penetration time of glove material:   | Gloves resistance is not critical when the product is handled according to the instructions for use.                               |
| Body protection   | Laboratory coat.   |
| Respiratory protection  | Not normally required.   |

## 8.2.3 Environmental Exposure Controls

No special measures are required.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance	Solid.
Colour	Blue and White.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not determined.
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not applicable.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not applicable.
Flammability (solid, gas)	Not determined.
Explosive limit ranges	Not applicable.
Vapour Pressure (Pascal)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not determined.
Solubility (Water)	Not applicable.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
Auto Ignition Temperature (°C)	Not determined.
Decomposition Temperature (°C)	Not determined.
Viscosity (mPa.s)	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising

### 9.2 Other information

Not available

## SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None known.
10.2 Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3 Possibility of hazardous reactions	None known. Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None
10.5 Incompatible materials	None known.
10.6 Hazardous Decomposition Product(s)	None known.

## ▶ SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### 11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.

STOT-repeated exposure	not met. Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.
<b>Health Effects and Symptoms</b>	
Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.
<b>11.2 Other information</b>	Not applicable.

## SECTION 12: ECOLOGICAL INFORMATION

<b>12.1 Toxicity</b>	The product does not contain significant quantities of ingredients that are environmentally toxic.
<b>12.2 Persistence and degradability</b>	The device contains plastic and other components that are not readily degradable
<b>12.3 Bioaccumulative potential</b>	No data.
<b>12.4 Mobility in soil</b>	No data.
<b>12.5 Results of PBT and vPvB assessment</b>	Not applicable.
<b>12.6 Other adverse effects</b>	Not applicable.

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>13.1 Waste treatment methods</b>	
<b>Product:</b>	Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<b>European waste catalogue:</b>	18 01 03.
<b>Packaging:</b>	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

## SECTION 14: TRANSPORT INFORMATION

<b>14.1 UN number</b>	Not applicable.
<b>14.2 UN Proper Shipping Name</b>	Not applicable.
<b>14.3 Transport hazard class(es)</b>	Not classified as dangerous for transport.
<b>14.4 Packing Group</b>	Not applicable.
<b>14.5 Environmental hazards</b>	Not applicable.
<b>14.6 Special precautions for user</b>	Not applicable.
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

## ▶ SECTION 15: REGULATORY INFORMATION

<b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
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### Carcinogen listings

IARC: None of the ingredients is listed.  
NTP: None of the ingredients is listed.  
ACGIH: None of the ingredients is listed.  
OSHA: None of the ingredients is listed.  
EPA: None of the ingredients is listed.

### Californian Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.  
Chemicals known to cause reproductive toxicity: None of the ingredients is listed.

### SARA

Section 355 (extremely hazardous substances): None of the ingredients is listed.  
Section 313 (specific toxic chemical listings): None of the ingredients is listed.

**15.2 Chemical Safety Assessment** Not applicable.

## SECTION 16: OTHER INFORMATION

### LEGEND

STOT Specific Target Organ Toxicity

### References:

Raw material safety data sheets.

### Additional Information

Reason for update:

SECTION 2: SECTION 4: SECTION 6: SECTION 7:  
SECTION 11: SECTION 15:

► Indicates altered section

Supersedes:

PN: 300130 Rev D

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