

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) | <i>In vitro diagnostic reagent. For professional use only.</i> |
| 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 | | Significant health effects are not anticipated from routine use of these materials when following the precautions listed within this SDS. None of the Research Reagents listed within this SDS are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), and the European Union. May cause slight skin irritation. |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- | | | |
|---------------------|-----------------------|---|
| 3.1 Mixtures | Description: | <i>In vitro diagnostic reagent. Aqueous solution.</i> |
| | 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 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 | < 0.1 |

- | | |
|-----------------------------------|--|
| 3.2 Additional Information | <p>There are no hazardous chemicals contained within this material at concentrations greater than 1% or 0.1% for extremely hazardous chemicals.</p> <p>Note: Sodium Azide is used as a preservative at concentrations <0.1%.</p> |
|-----------------------------------|--|

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|--------------|---|
| Inhalation | Supply fresh air. Consult a physician if any symptoms develop. |
| Skin Contact | Wash skin with soap and water. Consult a physician if irritation develops. |
| Eye Contact | Rinse cautiously with water for several minutes. Consult a physician if any symptoms develop. |
| Ingestion | Wash out mouth with water. Consult a physician if any symptoms develop. |

4.2 Most important symptoms and effects, both acute and delayed None known.

4.3 Indication of the immediate medical attention and special treatment needed None.

SECTION 5: FIRE-FIGHTING MEASURES

| | | |
|---|------------------------------|---|
| 5.1 Extinguishing media | Suitable Extinguishing Media | CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| 5.2 Special hazards arising from the substance or mixture | | In case of fire, the following can be released: Carbon oxides (CO _x), nitrogen oxides (NO _x), |
| 5.3 Advice for fire-fighters | | 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

| | | |
|---|--|--|
| 6.1 Personal precautions, protective equipment and emergency procedures | | Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage. |
| 6.2 Environmental precautions | | Do not allow the undiluted product to enter sewers/surface or ground water. |
| 6.3 Methods and material for containment and cleaning up | | 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. |
| 6.4 Reference to other sections | | 8, 13 |

SECTION 7: HANDLING AND STORAGE

| | | |
|--|--|---|
| 7.1 Precautions for safe handling | | Avoid contact with skin and eyes. Keep out of reach of children. Wash hands before breaks and after work. If aerosolization potential exists, handle under local exhaust ventilation such as a biological safety cabinet or fume hood. |
| 7.2 Conditions for safe storage, including any incompatibilities | | Store in the original container at 4 to 25°C. |
| 7.3 Specific end use(s) | | Use as per instructions for use. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. The exposure limits below apply to concentrated sodium azide only.

| Country | SUBSTANCE | CAS No. | LTEL (8 hr TWA mg/m ³) | STEL (mg/m ³) |
|----------------|----------------------------------|------------|---------------------------------------|---------------------------|
| United Kingdom | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Belgium | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Germany | Sodium azide As NaN ₃ | 26628-22-8 | 0.2 | 0.4 |
| Denmark | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.2 |
| France | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Spain | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Finland | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Ireland | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Italy | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Hungary | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Poland | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Lativa | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| Switzerland | Sodium azide As NaN ₃ | 26628-22-8 | 0.2 | 0.4 |
| Netherlands | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3 |
| USA | Sodium azide As NaN ₃ | 26628-22-8 | 0.1 | 0.3* |

*NIOSH Ceiling Limit

8.2 Exposure controls

8.2.1 Appropriate engineering controls

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. Avoid aerosolization. Handle under local exhaust ventilation if aerosolization potential exists.

8.2.2 Personal protection equipment

Eye/face protection

Safety glasses recommended during normal use. Use safety goggles if splash potential exists.

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. Avoid aerosolization. Handle under local exhaust ventilation if aerosolization potential exists.

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 | 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) | No data available.. |
| Flammability (solid, gas) | No data available.. |
| Explosive limit ranges | Not applicable. |
| Vapour Pressure (Pascal) | Similar to water, approximately 23 hPa. |
| Vapour Density (Air=1) | No data available.. |
| Density (g/ml) | ~1. |
| Solubility (Water) | Soluble. |
| Solubility (Other) | No data available.. |

| | |
|---|---------------------|
| Partition Coefficient (n-Octanol/water) | No data available.. |
| Auto Ignition Temperature (°C) | No data available.. |
| Decomposition Temperature (°C) | No data available.. |
| Viscosity (mPa.s) | No data available.. |
| Explosive properties | Not explosive. |
| Oxidising properties | Not oxidising |
| 9.2 Other information | No data 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 | Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur. |
| 10.4 Conditions to avoid | None |
| 10.5 Incompatible materials | Strong acids, strong bases, strong oxidizing agents. |
| 10.6 Hazardous Decomposition Product(s) | None known. |

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 Mixtures

| | |
|--------------------------------|--------------------|
| Acute toxicity | No data available. |
| Skin corrosion/irritation | No data available. |
| Serious eye damage/irritation | No data available. |
| Respiratory/skin sensitization | No data available. |
| Germ cell mutagenicity | No data available. |
| Carcinogenicity | No data available. |
| Reproductive toxicity | No data available. |
| STOT-single exposure | No data available. |
| STOT-repeated exposure | No data available. |
| Aspiration hazard | No data available. |

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

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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 available |
| 12.3 Bioaccumulative 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 |

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

SECTION 15: REGULATORY INFORMATION

| | | |
|------|--|--|
| 15.1 | Safety, health and environmental regulations/legislation specific for the substance or mixture | 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 |
| | 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): | Sodium azide. |
| | Section 313 (specific toxic chemical listings): | Sodium azide. |
| 15.2 | Chemical Safety Assessment | 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):



SAFETY DATA SHEET



According to Regulation (EC) No. 1907/2006 (REACH), Annex II

| | |
|-------------------|---|
| 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:

SDS Compliance

Supersedes:

PN: 300130 Rev E

Prepared by: Johnny Lim

Email: Johnny@occserv.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

| | | |
|--|---------------------------|---|
| 1.1 Product identifier | Trade name | NEPHROCHECK® Test Conjugate |
| 1.2 Relevant identified uses of the substance or mixture and uses advised against | Identified use(s) | <i>In vitro diagnostic reagent.</i> 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 | | Significant health effects are not anticipated from routine use of these materials when following the precautions listed within this SDS. None of the Research Reagents listed within this SDS are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), and the European Union. Handle as if potentially infectious. |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| | | |
|---------------------|------------------------|---|
| 3.1 Mixtures | 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

| | | |
|--|--------------|---|
| 4.1 Description of first aid measures | Inhalation | Supply fresh air; Consult a physician if any symptoms develop. |
| | Skin Contact | Wash skin with soap and water. Consult a physician if any symptoms develop. |
| | Eye Contact | Rinse cautiously with water for several minutes. Consult a physician if any symptoms develop. |
| | Ingestion | Wash out mouth with water. Consult a physician if any symptoms develop. |

- | | | |
|------------|---|-------------|
| 4.2 | Most important symptoms and effects, both acute and delayed | None known. |
| 4.3 | Indication of the immediate medical attention and special treatment needed | None. |

SECTION 5: FIRE-FIGHTING MEASURES

- | | | |
|------------|--|---|
| 5.1 | Extinguishing media Suitable Extinguishing Media | CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| 5.2 | Special hazards arising from the substance or mixture | In case of fire, the following can be released: Carbon oxides (CO _x). |
| 5.3 | Advice for fire-fighters | 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

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

SECTION 7: HANDLING AND STORAGE

- | | | |
|------------|---|--|
| 7.1 | Precautions for safe handling | This product should be handled as a potentially infectious material, as no known test method procedure can offer complete assurance that products derived from materials of human origin will not transmit infectious agents. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials. Follow universal precautions. Avoid contact with skin and eyes. Keep out of reach of children. Wash hands before breaks and after work. Clean work areas with hypochlorite or other disinfecting agent. If aerosolization potential exists, handle under local exhaust ventilation such as a biological safety cabinet or fume hood. |
| 7.2 | Conditions for safe storage, including any incompatibilities | Store in the original container at 4 to 25°C. |
| 7.3 | Specific end use(s) | Use as per instructions for use. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | | |
|--------------|---|--|
| 8.1 | Control parameters | |
| 8.1.1 | Occupational Exposure Limits | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| 8.2 | Exposure controls | |
| 8.2.1 | Appropriate engineering controls | If aerosolization potential exists, handle the material inside a biological safety cabinet or fume hood. |
| 8.2.2 | Personal protection equipment Eye/face protection | Safety glasses recommended. When in solution, use safety goggles if splash potential exists. |

| | |
|-------------------------------------|---|
| 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. Avoid aerosolization. Handle under local exhaust ventilation if aerosolization potential exists. |

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) | No data available.. |
| Melting Point (°C) / Freezing Point (°C) | No data available.. |
| Boiling point/boiling range (°C): | Not applicable. |
| Flash Point (°C) | Not applicable. |
| Evaporation rate (BA = 1) | Not applicable. |
| Flammability (solid, gas) | No data available. |
| Explosive limit ranges | Not applicable. |
| Vapour Pressure (Pascal) | Not applicable. |
| Vapour Density (Air=1) | Not applicable. |
| Density (g/ml) | No data available. |
| Solubility (Water) | Soluble. |
| Solubility (Other) | No data available. |
| Partition Coefficient (n-Octanol/water) | No data available. |
| Auto Ignition Temperature (°C) | No data available. |
| Decomposition Temperature (°C) | No data available. |
| 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 | No data available. |
| 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 | No data available. |
| 10.6 Hazardous Decomposition Product(s) | No data available. |

SECTION 11: TOXICOLOGICAL INFORMATION

| | |
|--|-------------------|
| 11.1 Information on toxicological effects | |
| 11.1.1 Mixtures | |
| Acute toxicity | No data available |
| Skin corrosion/irritation | No data available |
| Serious eye damage/irritation | No data available |
| Respiratory/skin sensitization | No data available |
| Germ cell mutagenicity | No data available |
| Carcinogenicity | No data available |
| Reproductive toxicity | No data available |

| | |
|------------------------------------|---|
| STOT-single exposure | No data available |
| STOT-repeated exposure | No data available |
| Aspiration hazard | No data available |
| 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 | The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. |
|-------------------------------|---|

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 available |
| 12.3 Bioaccumulative potential | No data available |
| 12.4 Mobility in soil | No data available |
| 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 | 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. |
| Product: | |
| European waste catalogue: | |
| Packaging: | 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

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

SECTION 15: REGULATORY INFORMATION

| | |
|--|--|
| 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture | 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 |
| 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 safety data sheets.

Additional Information

Reason for update: SDS Compliance
Supersedes: PN: 300130 Rev E

Prepared by: Johnny Lim, Email: Johnny@occserv.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

- 1.1 Product identifier**
Trade name NEPHROCHECK® Test Cartridge
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) *In vitro* diagnostic medical device. 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** Significant health effects are not anticipated from routine use of these materials when following the precautions listed within this SDS. None of the Research Reagents listed within this SDS are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), and the European Union. Handle as if potentially infectious.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Mixtures**
Description: *In vitro* 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

- 4.1 Description of first aid measures**
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.
- 4.2 Most important symptoms and effects, both acute and delayed** None known.
- 4.3 Indication of the immediate medical attention and special treatment needed** None.

SECTION 5: FIRE-FIGHTING MEASURES

- | | | |
|--|------------------------------|---|
| 5.1 Extinguishing media | Suitable Extinguishing Media | CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| 5.2 Special hazards arising from the substance or mixture | | In case of fire, the following can be released: Carbon oxides (CO _x), Hazardous fumes. |
| 5.3 Advice for fire-fighters | | 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

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

SECTION 7: HANDLING AND STORAGE

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- | | | |
|---|--|--|
| 8.1 Control parameters | | |
| 8.1.1 Occupational Exposure Limits | | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| 8.2 Exposure controls | | |
| 8.2.1 Appropriate engineering controls | | If aerosolization potential exists, handle the material in a biological safety cabinet or fume hood. |
| 8.2.2 Personal protection equipment | | |
| 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) | No data available. |
| | Melting Point (°C) / Freezing Point (°C) | No data available. |
| | Boiling point/boiling range (°C): | Not applicable. |
| | Flash Point (°C) | Not applicable. |
| | Evaporation rate (BA = 1) | Not applicable. |
| | Flammability (solid, gas) | No data available. |
| | Explosive limit ranges | Not applicable. |
| | Vapour Pressure (Pascal) | Not applicable. |
| | Vapour Density (Air=1) | Not applicable. |
| | Density (g/ml) | No data available. |
| | Solubility (Water) | Not applicable. |
| | Solubility (Other) | No data available. |
| | Partition Coefficient (n-Octanol/water) | No data available. |
| | Auto Ignition Temperature (°C) | No data available. |
| | Decomposition Temperature (°C) | No data available. |
| | 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 | No data available. |
| 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 | No data available. |
| 10.6 | Hazardous Decomposition Product(s) | No data available. |

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 Mixtures

| | |
|--------------------------------|--------------------|
| Acute toxicity | No data available |
| Skin corrosion/irritation | No data available |
| Serious eye damage/irritation | No data available. |
| Respiratory/skin sensitization | No data available. |
| Germ cell mutagenicity | No data available. |
| Carcinogenicity | No data available. |
| Reproductive toxicity | No data available. |
| STOT-single exposure | No data available |
| STOT-repeated exposure | No data available. |
| Aspiration hazard | No data available. |

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

The product is not subject to classification according to the calculation method of the General EU Classification

Guidelines for Preparations. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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 | The device contains plastic and other components that are not readily degradable |
| 12.3 Bioaccumulative 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 |

SECTION 13: DISPOSAL CONSIDERATIONS

| | |
|-------------------------------------|---|
| 13.1 Waste treatment methods | 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. |
| Product: | |
| European waste catalogue: | |
| Packaging: | 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

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

SECTION 15: REGULATORY INFORMATION

| | |
|--|--|
| 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture | 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 |
| Carcinogen listings | |
| IARC: | None of the ingredients is listed. |
| NTP: | None of the ingredients is listed. |
| ACGIH: | None of the ingredients is listed. |



SAFETY DATA SHEET



According to Regulation (EC) No. 1907/2006 (REACH), Annex II

| | |
|---|------------------------------------|
| 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 safety data sheets.

Additional Information

Reason for update: SDS Compliance

Supersedes: PN: 300130 Rev E

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