



SAFETY DATA SHEET

Version 2.0

Revision Date 11/16/2021

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

1.1 Product identifiers

Trade Name NEPHROCHECK® Test Kit EU IVD
Product Number 500003

Trade Name NEPHROCHECK® Test Kit US IVD
Product Number 500011

Trade Name NEPHROCHECK® Test Kit US IUO
Product Number 500004

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

Identified use(s) *in vitro* diagnostics (PN 500003 and 500011).
Investigational Use Only (PN 500004).

1.3 Details of the supplier of the safety data sheet

Company Astute Medical, Inc.
3550 General Atomics Ct.
Building 2
San Diego, CA 92121 USA
Telephone +1 (858) 500-7000
Email EHS.Astute@astutemedical.com

1.4 Emergency telephone

Emergency Phone No. +1 (855) 807-2783

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) & Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 GHS Label elements, including precautionary statements

Not a hazardous substance or mixture.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII. The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: *in vitro* diagnostic medical device. For professional use only.

Hazardous Components:

Substance	Formula	CAS No.	EC No.	W/W%
NEPHROCHECK® TEST CARTRIDGE				
Cellulose Nitrate	[C ₆ H ₇ (NO ₂) ₃ O ₅] _n	9004-70-0	682-719-5	~15%
Boric Acid	H ₃ BO ₃	10043-35-3	233-139-2	0.004%
Sodium Tetraborate Decahydrate	Na ₂ [B ₄ O ₅ (OH) ₄] ₁₀ H ₂ O	1303-96-4	215-540-4	0.012%
NEPHROCHECK® TEST BUFFER				
Sodium Azide	NaN ₃	26628-22-8	247-852-1	0.00045%
NEPHROCHECK® TEST CONJUGATE				
No hazardous substances or mixtures				100%

3.2 Additional Information

There are no hazardous chemicals contained within this material at concentrations greater than 1% or 0.1% for extremely hazardous chemicals. Sodium Azide is used as a preservative at concentrations <0.1%.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation

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

Skin Contact

Wash off with soap and plenty of water. Consult a physician.

Eye Contact

Rinse out with plenty of water. Remove contact lenses, if safe. Rinse eyes again.

Ingestion

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of the immediate medical attention and special treatment needed

No data available.



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SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

Use dry chemical, CO₂, water spray (fog) or alcohol resistant foam. Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Development of hazardous combustion gases or vapors possible in the event of fire. Fire may cause evolution of: oxides, nitrous gases

5.3 Advice for fire-fighters

Use fire-extinguishing methods suitable to surrounding conditions and consider the hazards of other involved materials. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires. Move containers from fire area if you can do so without risk.

Use water spray to cool unopened containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Keep away from sources of heat and ignition. For personal protection, see Section 8.

6.2 Environmental precautions

Do not allow the undiluted product to enter drains, sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

For liquid materials: Cover drains. Collect with liquid binding material (paper towelling, sand, diatomite, acid binders, etc.), and pump off spills. Observe possible material restrictions (see sections 7 and 10). Dispose of contaminated material as waste according to Section 13.

For dry materials: Take up dry components. Dispose of properly (See Section 13). Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

7, 8, 10, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on protection against fire and explosion:

For dry materials: keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

For liquid materials: Avoid contact with skin and eyes. 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 2 to 8°C. Dry.

Observe the expiration date.

Advice on common storage: Keep away from oxidizing agents, strongly alkaline and strongly acid materials in order to avoid exothermic reactions.

7.3 Specific end use(s)

Use as per instructions for use.



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits To our knowledge, the product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

SUBSTANCE	CAS No.	PEL (8 hr TWA mg/m ³)	STEL (mg/m ³) / Ceiling
Sodium Azide	26628-22-8	0.1	0.3*
Boric Acid	10043-35-3	2	6
Disodium Tetraborate, Anhydrous	1330-43-4	2	6

*NIOSH Ceiling Limit

8.2 Exposure controls US – California/ Tennessee OELs: Skin designation

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Sodium Azide (CAS 26628-22-8) Can be absorbed through the skin.

8.2.1 Appropriate engineering controls

Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment

Eye/face protection

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

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (avoid outer glove surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

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

Wear suitable protective clothing.

Respiratory protection

Not normally required. Avoid aerosolization. Handle under local exhaust ventilation if aerosolization potential exists. In case of insufficient ventilation, wear suitable respiratory equipment.

8.2.3 Environmental Exposure Controls

No special measures are required.



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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

NEPHROCHECK® TEST CARTRIDGE

Appearance	Solid. [Fibrous Sheets]
Color	White to yellowish.
Odor	No odor.
Odor Threshold (ppm)	Not applicable.
pH (Value)	No data available.
Melting Point (°C) / Freezing Point (°C)	No data available.
Boiling point/boiling range (°C):	No data available.
Flash Point (°C)	No data available.
Evaporation rate (BA = 1)	No data available.
Flammability (solid, gas)	Not a Combustible Solid.
Explosive limit ranges	No data available.
Vapor Pressure (Pascal)	Not applicable.
Vapor Density (Air=1)	No data available.
Density (g/ml)	No data available.
Solubility (Water)	Insoluble.
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.
Oxidizing properties	Not oxidizing.

NEPHROCHECK® TEST BUFFER

Appearance	Clear liquid.
Color	Colorless.
Odor	No odor.
Odor 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.
Vapor Pressure (Pascal)	Similar to water, approximately 23 hPa.
Vapor 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.
Oxidizing properties	Not oxidizing.



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NEPHROCHECK® TEST CONJUGATE

Appearance	Solid.
Color	White/Bluish.
Odor	No odor.
Odor 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.
Oxidizing properties	Not oxidizing.

9.2 Other information

NEPHROCHECK® TEST CARTRIDGE was found to be non-flammable when tested using N.1: Test Method for Readily Combustible Solids by an independent company.

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 and use conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Avoid sources of ignition (spark or flame).

10.5 Incompatible materials

Reactive or incompatible with the following materials: oxidizing materials, acids.

10.6 Hazardous Decomposition Product(s)

Under normal conditions of storage and use, hazardous decomposition products should not be produced.



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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	Direct contact with eyes may cause temporary irritation. However, eye exposure is not likely during normal use.
Ingestion	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

11.2 Other information

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.

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	No data available.
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	This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII.



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12.6 Other adverse effects

The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: DISPOSAL CONSIDERATIONS AND RECOMMENDATIONS

13.1 Recommended Waste Treatment Methods

Residual Waste:

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Packaging:

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste-handling site for recycling or disposal.

EU/US Waste code:

The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information:

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

Special precautions:

Dispose in accordance with all applicable regulations.

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 dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR
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 & environmental regulations/legislation specific for substance/mixture

OSHA Hazard Communication Standard 29 CFR 1910.1200

IVD Product Labelling 21 CFR 809.10 (c)(2) ii

Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008

Carcinogen listings

IARC:

None of the ingredients are listed.



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NTP:	None of the ingredients are listed.
ACGIH:	None of the ingredients are listed.
OSHA:	None of the ingredients are listed.
EPA:	None of the ingredients are listed.
Californian Proposition 65	
Chemicals known to cause cancer:	None of the ingredients are listed.
Chemicals known to cause reproductive toxicity:	None of the ingredients are listed.
SARA	
Section 355 (extremely hazardous substances):	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313 or 40 CFR 355.
Section 313 (specific toxic chemical listings):	

EU Regulations

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1, 2, and 3 and/or Annex V as amended: Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA: Not listed.

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended: Not listed.

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended: Not listed.

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

15.2 Chemical Safety Assessment

NEPHROCHECK® TEST CARTRIDGE was found to be non-flammable when tested using N.1: Test Method for Readily Combustible Solids by an independent company.

SECTION 16: OTHER INFORMATION

LEGEND

STEL	Short Term Exposure Limit
TEL (PEL)	Long Term Exposure limit (Permissible Exposure Limit)
TWA	Time Weighted Average
PBT	Persistent, bioaccumulative and toxic substance
vPvB	Very persistent and very bioaccumulative substance
W/W	All concentrations are in percent by weight except for nitrocellulose

Classification code(s):

None Applicable.



**ASTUTE
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References:

Raw material safety data sheets. Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). 40 CFR 355 Appendix A and B. Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-To-Know Act (EPCRA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Section 112(r) of the Clean Air Act.

Additional Information

Reason for update: Regular review against relevant regulation.

Supersedes: Rev G

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