



Trade Name: Bladder EpiCheck® DNA Extraction Kit

SECTION 1: Identification

Product identifier used on the label:

Product Name: Bladder EpiCheck® DNA Extraction Kit

Description: Includes reagents and Mini Spin Columns (packaged separately).

Other means of identification:

Part Number: NX899090-01US, including NX899090-04US (Mini Spin Columns)

Recommended use of the chemical and restrictions on use:

Recommended Use: Laboratory chemical for DNA extraction from cell pellet of urine samples. For professional users only.

Recommended Restrictions: Uses other than as recommended above

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party:

Company Name: Nucleix.
Company Address: 3 Pekeris Street,
7670203, Rehovot, Israel
Company Telephone: +972-8-9161616
Company Contact Email: support@nucleix.com

Emergency Phone Number: +972-8-9161616

SECTION 2: Hazard(s) Identification

The Bladder EpiCheck® DNA extraction kit consists of several reagents and consumables for DNA extraction from cell pellet of urine samples.

The kit consists of the following reagents: Buffer NL (2 x 12ml), Buffer NW1 (19ml), Buffer NW2 (13ml), Buffer NE (15ml), Protease (1 vial-lyophilized) and Protease solvent (1.2ml).

These are packaged in individual containers inside the same box.

For the purpose of this SDS, the overall classification is shown below. The classifications of each of the solutions can be found in section 2.2 under their separate subheadings.

Bladder EpiCheck® DNA extraction kit (as the whole kit)

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Physical hazards

None known

Bladder EpiCheck® DNA Extraction Kit

Health hazards

Acute toxicity, oral, category 4

Skin irritation, category 2

Serious eye irritation, category 2A

Acute toxicity, inhalation, category 4

Environmental hazards

Not adopted under OSHA paragraph (d) of §1910.1200

GHS Signal word: WARNING

GHS Hazard statement(s): H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H332 - Harmful if inhaled.

GHS Hazard symbol(s):



GHS Precautionary statement(s):

Prevention:

- P261 - Avoid breathing dust/fume/gas/mist/ vapors/spray.
- P264 - Wash thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P271 - Use only outdoors or in a well-ventilated area.
- P280 - Wear protective gloves /eye protection/face protection.

Response:

- P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell.
- P302+P352 - If on skin: Wash with plenty of water.
- P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P312 - Call a poison center/doctor if you feel unwell.
- P321 - Specific treatment (see sections 4 to 8 on this SDS and any further information on the label).
- P330 - Rinse mouth.
- P332+P313 - If skin irritation occurs: Get medical advice/attention.
- P337+P313 - If eye irritation persists: Get medical advice/attention.
- P362+P364 - Take off contaminated clothing and wash it before reuse.

Bladder EpiCheck® DNA Extraction Kit

Storage:

- None required.

Disposal:

- P501 - Dispose of contents/container to an approved disposal site in accordance with local/regional/national/ international regulations

Lysis Buffer NL:

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Physical hazards

None known

Health hazards

Acute toxicity, oral, category 4

Skin irritation, category 2

Skin sensitization, category 1

Serious eye irritation, category 2A

Acute toxicity, inhalation, category 4

Environmental hazards

Not adopted under OSHA paragraph (d) of §1910.1200

GHS Signal word:

WARNING

GHS Hazard statement(s):

H302 - Harmful if swallowed

H315 - Causes skin irritation

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

H332 - Harmful if inhaled.

GHS Hazard symbol(s):



GHS Precautionary statement(s):

Prevention:

- P261 - Avoid breathing dust/fume/gas/mist/ vapors/spray.
- P264 - Wash thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P271 - Use only outdoors or in a well-ventilated area.
- P272 - Contaminated work clothing must not be allowed out of the workplace.
- P280 - Wear protective gloves /eye protection/face protection.

Response:

- P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell.

Bladder EpiCheck® DNA Extraction Kit

- P302+P352 - If on skin: Wash with plenty of water.
- P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P312 - Call a poison center/doctor if you feel unwell.
- P321 - Specific treatment (see sections 4 to 8 on this SDS and any further information on the label).
- P330 - Rinse mouth.
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 - If eye irritation persists: Get medical advice/attention.
- P362+P364 - Take off contaminated clothing and wash it before reuse.

Storage:

- None required.

Disposal:

- P501 - Dispose of contents/container to an approved disposal site in accordance with local/regional/national/ international regulations

Buffer NW1

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Physical hazards

None known

Health hazards

Acute toxicity, oral, category 4

Skin irritation, category 2

Serious eye irritation, category 2A

Acute toxicity, inhalation, category 4

Environmental hazards

Not adopted under OSHA paragraph (d) of §1910.1200

GHS Signal word:

WARNING

GHS Hazard statement(s):

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H332 - Harmful if inhaled.

GHS Hazard symbol(s):

Bladder EpiCheck[®] DNA Extraction Kit



Bladder EpiCheck® DNA Extraction Kit

GHS Precautionary statement(s):

Prevention:

- P261 - Avoid breathing dust/fume/gas/mist/ vapors/spray.
- P264 - Wash thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P271 - Use only outdoors or in a well-ventilated area.
- P280 - Wear protective gloves /eye protection/face protection.

Response:

- P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell.
- P302+P352 - If on skin: Wash with plenty of water.
- P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P312 - Call a poison center/doctor if you feel unwell.
- P321 - Specific treatment (see sections 4 to 8 on this SDS and any further information on the label).
- P330 - Rinse mouth.
- P332+P313 - If skin irritation occurs: Get medical advice/attention.
- P337+P313 - If eye irritation persists: Get medical advice/attention.
- P362+P364 - Take off contaminated clothing and wash it before reuse.

Storage:

- None required.

Disposal:

- P501 - Dispose of contents/container to an approved disposal site in accordance with local/regional/national/ international regulations

Buffer NW2:

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Not classified as Hazardous under HCS 2012

GHS Signal word: None required.

GHS Hazard statement(s): Not classified as hazardous.

GHS Hazard symbol(s): None required.

GHS Precautionary statement(s): None required.

Bladder EpiCheck® DNA Extraction Kit

Buffer NE:

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Not classified as Hazardous under HCS 2012

GHS Signal word: None required.

GHS Hazard statement(s): Not classified as hazardous.

GHS Hazard symbol(s): None required.

GHS Precautionary statement(s): None required.

Protease (lyophilized):

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Physical hazards

None known

Health hazards

Serious eye damage, category 1

Respiratory sensitization, category 1

Environmental hazards

Not adopted under OSHA paragraph (d) of §1910.1200

GHS Signal word: DANGER

GHS Hazard statement(s): H318 - Causes serious eye damage.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS Hazard symbol(s):



GHS Precautionary statement(s):

Prevention:

- P261 - Avoid breathing dust/fume/gas/mist/ vapors/spray.
- P280 - Wear eye protection/face protection.
- P284 - [In case of inadequate ventilation] wear respiratory protection.

Response:

- P304+P340 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

Bladder EpiCheck® DNA Extraction Kit

- P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 - Immediately call a poison center/doctor.
- P342+P311 - If experiencing respiratory symptoms: Call a poison center/doctor.

Storage:

- None required.

Disposal:

- P501 - Dispose of contents/container to an approved disposal site in accordance with local/regional/national/ international regulations

Protease Solvent:

Classification of the chemical in accordance with paragraph (d) of §1910.1200:

Not classified as Hazardous under HCS 2012

GHS Signal word: None required.

GHS Hazard statement(s): Not classified as hazardous.

GHS Hazard symbol(s): None required.

GHS Precautionary statement(s): None required

Hazard(s) not otherwise

Classified (HNOC): None known.

Percentage of ingredient(s) of unknown acute toxicity:

Not applicable

SECTION 3: Composition / Information on Ingredients

Mixture:

Buffer NL:

Chemical name	CAS#	Concentration (weight %)
Guanidine hydrochloride	50-01-1	≥ 30 - < 50
Maleic acid	110-16-7	≥ 0.1 - < 1

Buffer NW1:

Chemical name	CAS#	Concentration (weight %)
Guanidine hydrochloride	50-01-1	≥ 50 - < 75

Bladder EpiCheck® DNA Extraction Kit

Buffer NW2:

There are no components above the threshold for classification as hazardous that require reporting in this section

Buffer NE:

There are no components above the threshold for classification as hazardous that require reporting in this section

Protease (lyophilized):

Chemical name	CAS#	Concentration (weight %)
Subtilisin	9014-01-1	$\geq 1 - < 10$

Protease solvent:

There are no components above the threshold for classification as hazardous that require reporting in this section

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.

SECTION 4: First-aid Measures

Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion:

Inhalation: Remove to fresh air. Perform artificial respiration if breathing has stopped. When breathing is difficult, properly trained personnel may administer oxygen. Keep affected person warm and at rest. Obtain medical attention.

Skin contact: Wash with plenty of water. Remove contaminated clothing. If skin irritation occurs, get medical attention. Launder contaminated clothing before reuse.

Eye contact: In case of eye contact, remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 mins. Get medical attention if symptoms develop.

Ingestion: Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Obtain medical attention immediately.

Most important symptoms/effects, acute and delayed:

Harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation

Indication of immediate medical attention and special treatment needed:

If any symptoms are observed, contact a physician and give them this SDS sheet.

Bladder EpiCheck® DNA Extraction Kit

SECTION 5: Fire-Fighting Measures

Suitable (and unsuitable) extinguishing media:

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: Do not use direct stream of water.

Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products):

In the event of fire and/or explosion do not breathe fumes. Exposure to decomposition products may be a hazard to health.

Hazardous combustion products may include the following substances: Carbon oxides, Nitrogen oxides (NO_x), Hydrogen chloride gas.

Special protective equipment and precautions for fire-fighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Wear other appropriate protective equipment as conditions warrant (see Section 8).

SECTION 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:

No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Avoid breathing vapors, mist, dust or gas. Wear appropriate protective equipment, such as gloves, goggles and protective clothing, as conditions warrant (see Section 8). See Sections 2 and 7 for additional information on hazards and precautionary measures.

Methods and materials for containment and cleaning up:

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has entered the environment, including waterways, soil or air. Materials can enter waterways through drainage systems.

Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Soak up with inert absorbent material (e.g., sand, silica gel, acid binder, universal binder, sawdust). Collect material in closed containers. Dispose of waste material using a licensed waste disposal contractor.

SECTION 7: Handling and Storage

Precautions for safe handling:

Avoid formation of aerosol. Do not breathe vapors/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. Smoking, eating and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations.

Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Bladder EpiCheck® DNA Extraction Kit

Wear appropriate protective equipment, such as gloves, goggles and protective clothing, as conditions warrant (see Section 8).

See Sections 2 and 7 for additional information on hazards and precautionary measures.

Conditions for safe storage, including any incompatibles:

Keep product in a dry, cool place. Keep away from incompatible materials (see Section 10) and food / feedstuffs. Protect container(s) against physical damage, heat and moisture. Do not allow material to contaminate ground water system. Prevent product from entering drains.

SECTION 8: Exposure Controls / Personal Protection

OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.

Substance	US OSHA PELs		US ACGIH TLVs		NIOSH OELs	
	TWA (8 hour)	STEL (15 min)	TWA (8 hour)	STEL (15 min)	IDLH	TWA (8hr)
Guanidine hydrochloride	None known	None known	None known	None known	None known	None known
Maleic acid	None known	None known	None known	None known	None known	None known
Subtilisin (as 100% crystalline active pure enzyme)	0,00006 mg/m ³ Ceiling	None known	0,00006 mg/m ³ Ceiling	None known	None known	0,00006 mg/m ³ Ceiling

Appropriate engineering controls:

Use material in well-ventilated area only. If exposure limits have not been established, maintain airborne levels to an acceptable level. Use appropriate personal protective equipment and clothing to avoid skin contact.

Individual protection measures, such as personal protective equipment:

Eye/face protection: Wear safety glasses. Wear face-shield and protective suit for abnormal processing problems. Ensure that eyewash stations and safety showers are close to the workstation location.

Skin and hand protection: Choose body protection according to the amount and concentration of the dangerous substance at the workplace. Use footwear protecting against chemicals.

Use impervious gloves. The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

Bladder EpiCheck® DNA Extraction Kit

Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer 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.

Respiratory protection: Under normal working conditions, wear a mask for protection. Local exhaust or general ventilation adequate to maintain exposures below appropriate exposure limits. In the case of vapor formation use a respirator with an approved filter. Only use respirators and components tested and approved under appropriate government standards.

General hygiene considerations: Keep out of eyes. Use general hygiene measures.

SECTION 9: Physical and Chemical Properties

Appearance (physical state, color, etc.):

Physical state:	Liquid / Solid
Color:	No data available
Odor:	Characteristic
Odor threshold:	Not determined
pH:	4.5 - 9
Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	Not determined
Flash point:	Not determined
Evaporation rate:	Not determined
Flammability (solid, gas):	Not expected to be flammable
Upper/lower flammability or explosive limits	
Flammability limit – lower (%):	Not determined
Flammability limit – upper (%):	Not determined
Explosive limit – lower (%):	Not determined
Explosive limit – upper (%):	Not determined
Vapor pressure:	Not determined
Vapor density:	Not determined
Relative density:	1 - 1.168 g/cm ³
Solubility (ies):	Soluble (Protease solvent)
Partition coefficient (n-octanol/water):	Not determined
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
Viscosity:	Not determined

Bladder EpiCheck® DNA Extraction Kit

SECTION 10: Stability and Reactivity

Reactivity:	Not expected to be reactive.
Chemical stability:	Stable under normal ambient and anticipated conditions of use
Possibility of hazardous reactions:	Hazardous reactions not anticipated under normal temperature and pressures.
Conditions to avoid:	No data available.
Incompatible materials:	Avoid contact with strong oxidizing agents, acidic or alkaline products.
Hazardous decomposition Products:	No decomposition if stored and applied as directed. Hazardous decomposition products formed under fire Conditions - Carbon oxides, Nitrogen oxides (NO _x), Hydrogen chloride gas

SECTION 11: Toxicological Information

Information on likely routes of exposure:

Inhalation: Expected to be a route of exposure.

Ingestion: Expected to be a route of exposure.

Skin: Expected to be a route of exposure.

Eyes: Expected to be a route of exposure.

Symptoms related to the physical, chemical, and toxicological characteristics:

Harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation.

Delayed and immediate effects and chronic effects from short or long-term exposure:

Other than the symptoms above, no further effects are known.

Numerical measures of toxicity (such as acute toxicity estimates):

Product/ingredient name	Test	Species	Dose
Guanidine hydrochloride	LD ₅₀ Oral	Rat	907.1 mg/kg
	LD ₅₀ Dermal	Rabbit	> 2000 mg/kg
	LC ₅₀ Inhalation	Rat	35.319 mg/L (4h)
Maleic acid	LD ₅₀ Oral	Rat	2870 mg/kg
	LD ₅₀ Dermal	Rabbit	398-1000 mg/kg
	LC ₅₀ Inhalation	Rat	> 0.72 mg/l (1h)
Subtilisin	LD ₅₀ Oral	Rat	1728 mg/kg
	LD ₅₀ Dermal	Rabbit	None known
	LC ₅₀ Inhalation	Rat	None known

Acute toxicity: Harmful if swallowed or if inhaled.

Skin corrosion/irritation: Causes skin irritation.

Bladder EpiCheck® DNA Extraction Kit

Serious eye damage/eye irritation:	Causes serious eye irritation.
Respiratory or skin sensitization:	One of the components of this product may cause allergy or asthma symptoms or breathing difficulties if inhaled (subtilisin) One of the components of this product may cause an allergic skin reaction (Maleic acid).
Germ cell mutagenicity:	Not expected to cause genetic defects.
Carcinogenicity:	Not expected to cause carcinogenic defects
Reproductive toxicity:	Not expected to cause reproductive toxicity.
STOT – Single exposure:	Not expected to cause specific target organ toxicity after single exposure.
STOT – Repeat exposure:	Not expected to cause specific target organ toxicity after prolonged or repeated exposure.
Aspiration hazard:	Not expected to be an aspiration hazard.

SECTION 12: Ecological Information

Ecotoxicity (aquatic and terrestrial, where available):

Harmful to aquatic life.

Substance name	Toxicity to fish / other aquatic invertebrates
Guanidine hydrochloride	LC50 - Leuciscus idus - 1,758 mg/l – 48h EC50 - Daphnia magna – 70.2 mg/l - 48 h EC50 - Desmodesmus subspicatus – 11.8 mg/l -72 h
Maleic acid	LC50 - Leuciscus idus - 106 mg/l - 48 h EC50 - Daphnia magna – 42.81 mg/l - 48 h EC50 - Freshwater Algae – 74.32 mg/l -72 h
Subtilisin	LC50 - Oncorhynchus mykiss- 15.6 mg/l - 96 h EC50 - Daphnia magna – 0.327 mg/l - 48 h EC50 - Desmodesmus subspicatus – > 1509 mg/l -72 h

Persistence and Degradability:

Not established

Bioaccumulative Potential:

Partition coefficient: n- octanol/water - log Pow: ca. -1.7 (20 °C) (guanidine hydrochloride)

Mobility in Soil:

Not established.

Bladder EpiCheck® DNA Extraction Kit

Other adverse effects (such as hazardous to the ozone layer):

Avoid release to the environment.

SECTION 13: Disposal Considerations

Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.

Product

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Contaminated packaging

Contaminated packaging may contain traces of the product. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Avoid dispersal of spilled material and runoff, and contact with soil, waterways, drains and sewers.

SECTION 14: Transport Information

US Department of Transportation Classification (49CFR)

Not regulated under DOT.

IMDG (Transport by sea)

Not regulated under IMDG.

IATA (Country variations may apply)

Not regulated under IATA.

Environmental hazards

Marine pollutant: No

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)

No further relevant information is available.

Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises.

None known.

SECTION 15: Regulatory Information

USA:

United States Federal Regulations: This SDS complies with the OSHA, 29 CFR 1910.1200. The product is classified as hazardous under OSHA.

Toxic Substances Control Act (TSCA) – All of the ingredients are listed on the U.S. EPA TSCA Inventory List.

Emergency Planning and Community Right To-Know Act (EPCRA)

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None listed

Bladder EpiCheck® DNA Extraction Kit

SARA HAZARD DESIGNATION SECTIONS 311/312 (40 CFR 370 (amended 2018)):

Serious eye damage or eye irritation.
Respiratory or skin sensitization

Section 313 Toxic Chemicals (40 CFR 372.65):

None of the components are listed

STATE REGULATIONS:

This SDS contains specific health and safety data that is applicable for state requirements. For details on your regulatory requirements, you should contact the appropriate agency in your state.

California Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986): None of the components are listed

Massachusetts Right to Know: Maleic acid is listed on the Massachusetts Right to Know list.

New Jersey Right to Know Maleic acid is listed on the New Jersey Right to Know List.

Pennsylvania Right to Know: Maleic acid is listed on the Pennsylvania Right to Know List.

SECTION 16: Other Information

Revision Date: June 26, 2023

DISCLAIMER:

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.