

Material Safety Data Sheet

Product	Uromonitor®
Report Number	MSDS-UROM-001
Date	v1.1: 2022-11-16
Updates	v1.2: 2024-07-02
Responsible	U-Monitor, Lda

The Uromonitor® is an IVD test, intended to detect and monitor non-muscle invasive bladder carcinoma recurrence by detecting hotspot mutations in the TERTp, FGFR3 and KRAS genes in DNA derived from exfoliated cells present in urine.

Samples are processed using the Urine Filtration kit (#Urokit1), DNA extraction and preparation kit (#Urokit2) and Real-Time PCR kit for TERT, FGFR3 and KRAS mutations detection (#Urokit3).

This product contains two subunits with related SDS, listed below. You can find the SDS for each component on the following pages.

Subunits with SDS:

- DNA extraction and preparation kit (#Urokit2).
- Real-Time PCR kit for TERT, FGFR3 and KRAS mutations detection (#Urokit3).

1. Identification

1.1. Product Identifier

Product Name: Uromonitor® - DNA extraction and preparation kit (#UROKIT2)
Product Number(s): #UROKIT2 (PADNP25, PADNP50)
Brand: U-Monitor
Identified uses: Laboratory chemicals. In vitro Diagnostics (IVD).

1.2. Company

Supplier: STELLA MARIS MEDICAL - ALERTS, LDA.
Centro de Incubação da Maia – Trv, das Cruzes do Monte nr 46
4470-169 Maia, Portugal
Telephone: +351 227 662 332
VAT: PT514343516

Manufacturer: INFOGENE, Lda.
Rua Pedro Nunes, Instituto Pedro Nunes, TecBis, Edifício D
3030-199 Coimbra, Portugal
Telephone: +351 239 700 327
VAT: PT 507766393

1.3. Emergency telephone number:

Emergency telephone number: +351-808 250143
(Poison Information Centre, CIAV, Lisbon) or check
local emergency contact information

2. Hazards Identification

2.1. Uromonitor® - DNA extraction and preparation kit (#UROKIT2)

2.1.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Acute Toxicity: Category 4, H302

Eye Irritant: Category 2A, H319

Skin irritation: Category 2: H315

Specific target organ toxicity – single exposure (STOT-SE): Category 3, Respiratory System, H335

2.1.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Hazard pictograms:



Signal word: Warning

Hazard Statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

Precautionary statements (response):

P330	IF swallowed: Rinse mouth.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position 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 so. Continue rinsing.

Prevention:

P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
P281	Use personal protective equipment as required.

2.1.3. Other hazards

None

3. Composition/information on ingredients

3.1. Uromonitor® - DNA extraction and preparation kit (#UROKIT2)

3.1.1. Composition/information on ingredients

3.1.1.1. Description

Kit used for the purification of DNA from exfoliated cells present in urine, containing several separated buffers/mixtures/ ingredients.

3.1.1.2. Chemical Characterization: Mixtures, Ingredients.

Mixture (s) / Ingredients	Reagent	CAS	EC-No	%	Classification (CLP)
Cell Lysis Buffer	Guanidine Thiocyanate	593-84-0	209-812-1	5.0-10	Acute Tox.4;H302 Skin Irrit. 2; H315 Eye Irrit 2; H319 STOT SE 3; H335
Cell Lysis Buffer	Sarkosyl	137-16-6	205-281-5	0.5-2.0	Acute Tox.4;H302 Skin Irrit. 2; H315 Eye Irrit 2; H319 STOT SE 3; H335
Normalizing Solution	Potassium Acetate	127-08-2	204-822-2	5.0-10	Acute Tox.4;H302 Skin Irrit. 2; H315 Eye Irrit 2; H319 STOT SE 3; H335
Washing Solutions	Tris-HCl	1185-53-1	214-684-5	0.1-1.0	Acute Tox.4;H302 Skin Irrit. 2; H315 Eye Irrit 2; H319

Washing Solution 1	Guanidine-HCL	50-01-1	200-002-3	5.0-10	Acute Tox.4;H302 Skin Irrit. 2; H315 Eye Irrit 2; H319
Proteinase K	Proteinase K	39450-01-6	254-457-8	≤100	Skin Irrit.2, H315 Eye Irrit.2, H319 Resp. Sens.1, H334 STOT SE 3, H335

All the other components not listed here are either not dangerous or their concentrations do not exceed the limits specified in Regulation (EC) Bo 1272/2008.

4. First aid measures

General information:	Consult a physician. Show this safety data sheet to the doctor in attendance
Inhalation:	If inhaled, move exposed person to fresh air. If not breathing, begin artificial respiration immediately and obtain medical attention.
Eye contact:	In case of contact with eyes, rinse with plenty of water for at least 15 minutes. Remove contact lenses. If pain or irritation occurs obtain medical attention.
Skin contact:	In case of contact with skin, flush with copious amounts of water for at least 15 minutes. If pain or irritation occurs obtain medical attention.
Ingestion:	If swallowed, wash mouth with water. If irritation or discomfort occurs, obtain medical attention

5. Fire-fighting measures

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during firefighting:	Exposure to decomposition products may be a hazard to health.
Hazardous combustion products:	No hazardous combustion products are known.

Further information: In the event of fire and/or explosion do not breathe fumes.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. Ensure adequate ventilation.

Environmental Precautions: Avoid spill to prevent migration. Do not allow product to enter drains. Dispose of contents/container in accordance to national and local regulations.

Methods and materials for containment and cleaning up: Keep in suitable, closed containers for disposal.

7. Handling and storage

Advice on protection against fire and explosion: Normal measures for preventive fire protection.

Advice on safe handling: For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.

Further information on storage stability: No decomposition if stored and applied as directed.

8. Exposure controls/ personal protection

8.1. Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2. Personal protective equipment

Hand protection:	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).
Eye protection:	Safety glasses.
Skin and body protection:	Choose body protection according to the amount and concentration of the dangerous substance at the workplace. Footwear protecting against chemicals.
Respiratory protection:	Avoid aerosol production and inhalation.
Hygiene measures:	Keep away from food and drink. When using do not eat, drink, or smoke.

9. Physical and chemical properties

Appearance:	Liquid
Color:	Colorless
Odor:	Odorless
pH (20°C):	7.5-8.5
Melting point:	Undetermined
Boiling point:	Undetermined
Flash point:	Undetermined
Self-ignition:	Product is not self-igniting
Danger of explosion	Does not present an explosion hazard
Density	Undetermined
Water solubility	Miscible

10. Stability and reactivity

Reactivity:	No decomposition if stored and applied as directed.
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Chemical Stability:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions:	No decomposition if stored and applied as directed.
Conditions to avoid:	Undetermined
Materials to avoid:	Undetermined
Hazardous decomposition products:	No decomposition if stored and applied as directed.
Hazardous products of thermal decomposition:	No decomposition if stored and applied as directed.

11. Toxicological information

Acute toxicity:	Harmful if swallowed
Irritation:	Causes skin irritation. Causes serious eye irritation.
Corrosivity:	Undetermined
Sensitization:	Undetermined
Germ cell mutagenicity:	Undetermined
Carcinogenicity:	No component of this product present is identified as probable possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	Undetermined
Specific target organ toxicity (single exposure):	May cause respiratory irritation
Specific target organ toxicity (repeated exposure):	Undetermined
Aspiration hazard:	Undetermined

12. Ecological information

Aquatic toxicity:	No further relevant information available.
Persistence and degradability:	No further relevant information available.

Bioaccumulative potential: No further relevant information available.
Mobility in Soil: No further relevant information available.
Other adverse effects: No further relevant information available.

Results of PBT and vPvB assessment: This product does not contain any substances that are assessed to be a PBT or a vPvB.

13. Disposal considerations

Waste from residues: Do not dispose waste into drains.
Dispose hazardous waste in compliance with local and national regulations.
Contaminated packaging: Dispose contents/ containers to an approved waste handling site for recycling or disposal.

14. Transport information

IATA/ADR/DOT-US/IMDG

Not regulated in the meaning of transport regulations

14.1. UN number

No dangerous good in sense of transport regulation

14.2. UN proper shipping name

Not dangerous goods

14.3. Additional information

No supplementary information available

Land transport ADR/RID (cross-border)

Not dangerous goods

Maritime transport IMDG

Not dangerous goods

Air transport ICAO-TI and IATA-DGR

Not dangerous goods

15. Regulatory information

15.1. US Federal Regulations

No additional information available

15.2. International Regulations

EU Regulations

No additional information available

Classification according to Regulation (EC) No 1272/2008 [CLP]

No additional information available

15.3. National Regulations

No additional information available

15.4. US State Regulations

No additional information available

15.5. Other Regulations

No additional information available

16. Other information

The information mentioned above is based on our present knowledge and is believed to be correct.

In the event of an accident involving exposure of staff to the material contained in the samples, contact the STELLA MARIS MEDICAL - ALERTS, LDA. (+351 227 662 332) during normal PT working hours. Refer to section 1 for full contact details.

The above information is correct to the best of our knowledge. All materials and mixtures may present unknown hazards and should be used with caution.

The user should make independent assessments and decisions regarding the completeness of the information based on all sources available.

The STELLA MARIS MEDICAL - ALERTS, LDA. shall not be held liable for any damage resulting from handling or contact with the above product.

1. Identification

1.1. Product Identifier

Product Name: Uromonitor® - Real-Time PCR kit for TERT, FGFR3 and KRAS mutations detection (#UROKIT3)

Product Number(s): #UROKIT3 (PRTPCR25, PRTPCR50)

Brand: U-Monitor

Identified uses: Laboratory chemicals. In vitro Diagnostics (IVD).

1.2. Company

Supplier: STELLA MARIS MEDICAL - ALERTS, LDA.
Centro de Incubação da Maia – Trv, das Cruzes do Monte nr 46
4470-169 Maia, Portugal
Telephone: +351 227 662 332
VAT: PT514343516

Manufacturer: INFOGENE, Lda.
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3030-199 Coimbra, Portugal
Telephone: +351 239 700 327
VAT: PT 507766393

1.3. Emergency telephone number:

Emergency telephone number: +351-808 250143
(Poison Information Centre, CIAV, Lisbon) or check
local emergency contact information

2. Hazards Identification

2.1. Uromonitor® - Real-Time PCR kit for TERT, FGFR3 and KRAS mutations detection (#UROKIT3)

2.1.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

This mixture is not classified as dangerous.

2.1.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

NC Not Classified

2.1.3. Other hazards

Some hazards associated with individual components of this mixture are not relevant because the substances are present in concentrations below the GHS cut-off levels, change of physical state or because the mixture/ solution is buffered to pH 4-9 (see GHS Directive 1272/2008/EC Annex I, chapter 3.2.3.1.2.).

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. Composition/information on ingredients

3.1. Uromonitor® - Real-Time PCR kit for TERT, FGFR3 and KRAS mutations detection (#UROKIT3)

3.1.1. Composition/information on ingredients

3.1.1.1. Description

This kit provides the reagents for the amplification and detection of mutations in the TERT promoter (-124 and -146), FGFR3 codons 248, 249, 372 and 375, and KRAS codons 12/13 and 61, through a highly sensitive and specific Real-Time PCR method. These reagents include DNA oligonucleotides diluted in DNase/RNase free distilled water.

3.1.1.2. Chemical Characterization: Mixtures, Ingredients.

Mixture (s) / Ingredients	Reagent	CAS	EC-No	%	Classification (CLP)
Glycerol, 1,2,3-Propanetriol Glycerin C3H8O3	Mastermix (RMT, RMF, RMK)	56-81-5	200-289-5	<1%	Not a hazardous substance or mixture
Primers and probes	DNA Oligonucleotides	n/a	n/a	n/a	Not a hazardous substance or mixture
DNA controls	DNA Oligonucleotines	n/a	n/a	n/a	Not a hazardous substance or mixture
dH2O	DNase/RNase free distilled Water	7732-18-5	231-791-2	n/a	Not a hazardous substance or mixture

All the other components not listed here are either not dangerous or their concentrations do not exceed the limits specified in Regulation (EC) Bo 1272/2008.

4. First aid measures

General information:	Consult a physician. Show this safety data sheet to the doctor in attendance
Inhalation:	If inhaled, move exposed person to fresh air. If not breathing, begin artificial respiration immediately and obtain medical attention.
Eye contact:	In case of contact with eyes, rinse with plenty of water for at least 15 minutes. Remove contact lenses. If pain or irritation occurs obtain medical attention.
Skin contact:	In case of contact with skin, flush with copious amounts of water for at least 15 minutes. If pain or irritation occurs obtain medical attention.
Ingestion:	If swallowed, wash mouth with water. If irritation or discomfort occurs, obtain medical attention

5. Fire-fighting measures

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during firefighting:	Exposure to decomposition products may be a hazard to health.
Hazardous combustion products:	No hazardous combustion products are known.
Further information:	In the event of fire and/or explosion do not breathe fumes.
Special protective equipment for fire-fighters:	Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:	Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. Ensure adequate ventilation.
Environmental Precautions:	Avoid spill to prevent migration. Do not allow product to enter drains. Dispose of contents/container in accordance to national and local regulations.
Methods and materials for containment and cleaning up:	Keep in suitable, closed containers for disposal.

7. Handling and storage

Advice on protection against fire and explosion:	Normal measures for preventive fire protection.
Advice on safe handling:	For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.
Further information on storage stability:	No decomposition if stored and applied as directed.

Note: This kit is shipped on dry ice. It is recommended that the user handle the samples using appropriate personal protective equipment such as insulated gloves. In its solid-state dry ice will quickly cause serious freeze damage, so contact with skin should be avoided. Any dry ice should be allowed to evaporate in a well-ventilated area. Do not dispose of dry ice in a sealed container. Personal protective equipment comprised of laboratory coat, disposable latex/plastic gloves and safety glasses should be worn when handling (unpacking) DNA oligonucleotides.

8. Exposure controls/ personal protection

8.1. Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2. Personal protective equipment

Hand protection:	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).
Eye protection:	Safety glasses.
Skin and body protection:	Choose body protection according to the amount and concentration of the dangerous substance at the workplace. Footwear protecting against chemicals.
Respiratory protection:	Avoid aerosol production and inhalation.
Hygiene measures:	Keep away from food and drink. When using do not eat, drink, or smoke.

9. Physical and chemical properties

Appearance:	Liquid when thawed, solid when frozen
Color:	Colorless
Odor:	Odorless

pH (20°C):	Undetermined
Melting point:	Undetermined
Boiling point:	Undetermined
Flash point:	Undetermined
Self-ignition:	Product is not self-igniting
Danger of explosion	Does not present an explosion hazard
Density	Undetermined
Water solubility	Soluble

10. Stability and reactivity

Reactivity:	No decomposition if stored and applied as directed.
Stability:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions:	No potentially hazardous reactions known.
Conditions to avoid:	Extremely high or low temperatures.
Materials to avoid:	Acid chlorides, Phosphorus halides, Strong acids, Bases, Oxidizing agents, Reducing agents, Alkali metals.
Hazardous decomposition products:	No decomposition if stored and applied as directed.
Hazardous products of thermal decomposition:	No decomposition if stored and applied as directed.

11. Toxicological information

Acute toxicity:	Based on available data the classification criteria are not met
Irritation:	Based on available data the classification criteria are not met
Corrosivity:	Based on available data the classification criteria are not met
Sensitization:	Based on available data the classification criteria are not met
Germ cell mutagenicity:	Based on available data the classification criteria are not met

Carcinogenicity:	No component of this product present is identified as probable possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	Based on available data the classification criteria are not met
Specific target organ toxicity (single exposure):	Based on available data the classification criteria are not met
Specific target organ toxicity (repeated exposure):	Based on available data the classification criteria are not met
Aspiration hazard:	Based on available data the classification criteria are not met

12. Ecological information

Aquatic toxicity:	Undetermined
Persistence and degradability:	Undetermined
Bioaccumulative potential:	Undetermined
Mobility in soil:	Undetermined
Other adverse effects:	Undetermined

Not regarded as dangerous for the environment. However, large or frequent spills may have hazardous effects on the environment.

13. Disposal considerations

Waste from residues:	Do not dispose waste into drains. Dispose hazardous waste in compliance with local and national regulations.
Contaminated packaging:	Dispose contents/ containers to an approved waste handling site for recycling or disposal.

14. Transport information

IATA/ADR/DOT-US/IMDG

#UROKIT3 is not classified as dangerous goods and as it is non-infectious to humans or animals, it is not subject to IATA or ADR regulation for dangerous goods. Not regulated in the meaning of transport regulations.

14.1. UN number

1845 - applicable to dry ice if #UROKIT3 is transported frozen

14.2. UN proper shipping name

Dry ice

14.3. Additional information

No supplementary information available

Land transport ADR/RID (cross-border)

Not dangerous goods

Maritime transport IMDG

Not dangerous goods

Air transport ICAO-TI and IATA-DGR

Not dangerous goods

15. Regulatory information

15.1. US Federal Regulations

No additional information available

15.2. International Regulations

EU Regulations

No additional information available

Classification according to Regulation (EC) No 1272/2008 [CLP]

No additional information available

15.3. National Regulations

No additional information available

15.4. US State Regulations

No additional information available

15.5. Other Regulations

No additional information available

16. Other information

The information mentioned above is based on our present knowledge and is believed to be correct.

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The above information is correct to the best of our knowledge. All materials and mixtures may present unknown hazards and should be used with caution.

The user should make independent assessments and decisions regarding the completeness of the information based on all sources available.

The STELLA MARIS MEDICAL - ALERTS, LDA. shall not be held liable for any damage resulting from handling or contact with the above product.