

According to Regulation (EU) No. 1907/2006

Revision date: 13-03-2023 Date of issue: 13-03-2023

Version: 9

Identification of the substance/mixture and the company/undertaking

1.1. Product identifier

Product name: LabStrip U11 Plus urine test strip

LabStrip U11 Plus GL urine test strip LabStrip U11 Plus MD urine test strip LabStrip U mALB/CREA urine test strip LabStrip U12 mALB/CREA urine test strip LabStrip U12 mALB/CREA MD urine test strip

Product code / Catalog No. / REF:

ANA-9901-1, ANA-9903-1, ANA-9906-1, ANA-9908-1, ANA-9909-4, ANA-9910-1,

ANA-9914-1, ANA-9915-1, ANA-9918-1 (49935)

ANA-9901GL-1, ANA-9903GL-1, ANA-9908GL-1, ANA-9909GL-3, ANA-9910GL-1,

ANA-9914GL-1, ANA-9918GL-1 (50191)

ACR-9901-1, ACR-9902-1

U12-9901-1 U12-9902-1 (56247)

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

1.2.1. Relevant identified uses:

Use of substance / mixture: In vitro diagnostic. Multiple parameters urine test strip. For professional use only.

1.2.2. Uses advised against:

Uses advised against: No additional information available.

1.3. Details of supplier of the safety data sheet

Company name: 77 Elektronika KFT

Company address: 1116, Budapest, Fehérvári út 98., Hungary

 Technical telephone:
 +36-1-2061480

 Fax:
 +36-1-2061481

 E-mail:
 sales@e77.hu

 Internet:
 www.e77.hu

1.4. Emergency telephone number

Emergency number: During working hours (CET: 8:00-- 16:35)

+36-1-2061480 (in Hungarian, English and German languages) ugyfelszolgalat@e77.hu (in Hungarian, English and German languages)

2. Hazards Identification

Warnings: The usual precautions taken when handling chemicals should be observed.

2.1. Classification of the substance or mixture

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

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements

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

Hazard pictograms (CLP):

Signal word (CLP):

Hazard statements (CLP):

This product holds no significant risks for human beings and environment.

This product holds no significant risks for human beings and environment.

This product holds no significant risks for human beings and environment.

This product holds no significant risks for human beings and environment.

This product holds no significant risks for human beings and environment.

2.3. Other hazards

Other hazards: No additional information available.

3. Composition, information on ingredients

3.1. Substance

Substance: Not applicable.



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3.2. Mixture

A tube contains: 25 or 150 pcs test strips (1x) (No hazards in declaration liability concentrations.)

Chemical characterization: Urine Test Strips for the Rapid Determination of Ascorbic Acid, Bilirubin, Blood, Glucose,

Ketones, Leucocytes, Nitrite, pH-value, Protein, Specific Gravity, Urolilinogen and/or Albumin and Creatinine. Refer to the carton and label for specific parameter combination

on the product you are using.

Classification: This mixture is not classified as dangerous according to Regulation (EC) No. 1907/2006.

3.3. Specific concentration limits:

No hazardous components.

4. First aid measures

4.1. Description of first aid measures

General information: No administration in cases of unconsciousness or cramps. Move victim out of danger

zone.

First aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical

advice (show the label where possible).

First aid measures after inhalation: Provide fresh air. When symptoms occur go into open air and ventilate suspected area

First aid measures after skin contact: After contact with skin, wash immediately with water. Remove contaminated clothing.

Drench affected area with water for at least 15 minutes.

First aid measures after eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Rinse cautiously with

water for several minutes. Remove contact lenses, if present and easy to do. Continue

rising.

First aid measures after ingestion: Rinse mouth thoroughly with water. Consult physician immediately. Rinse mouth. Do NOT

induce vomiting.

General advice: Show this safety data sheet to the doctor in attendance.

Do not leave the victim unattended.

Advice to doctor: Treat symptomatically.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms / injuries: May cause an allergic reaction in sensitive individuals.

Symptoms / injuries after inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of

normal use

Symptoms / injuries after skin contact: May cause sensitization of susceptible persons by skin contact.

Symptoms / injuries after eye contact: May cause eye irritation.

Symptoms / injuries after ingestion: If a large quantity has ingested: May cause nausea, vomiting and diarrhea.

Chronic symptoms: None expected under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

If medical advice is needed, have product container or label at hand.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media: Extinguishing materials should be selected according to the surrounding area.

Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.

Extinguishing media which must be used for No restriction. None known.

safety reasons:

5.2. Special hazards arising from the substance or mixture

Fire hazard: Not flammable.

Explosion hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Combustion products, resulting gases: No risks worthy of mention.

5.3. Advice for firefighters

Firefighting instructions: Exercise caution when fighting any chemical fire.

Protection during firefighting: In case of fire wear self-contained breathing apparatus. Do not enter fire area without

proper protective equipment, including respiratory protection.



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Accidental release measures

Personal precautions, protective equipment and emergency procedures 6.1.

Refer to chapter 7 No further action is necessary.

For non-emergency personnel 6.1.1.

Use appropriate personal protection equipment (PPE). Protective equipment:

Emergency procedures: Evacuate unnecessary personnel.

6.1.2. For emergency personnel

Equip clean crew with proper protection. Protective equipment:

Emergency procedures: Ventilate area.

6.2. **Environmental precautions**

Prevent entry to sewer and public waters.

Do not empty into drains of the aquatic environment.

Prevent spreading over great surfaces (e.g. by damming or installing oil booms).

Methods and material for containment and cleaning up 6.3.

Absorb and/or contain spill with inert material, then place in suitable container. For containment:

Methods for cleaning up: Do not allow to enter into soil/subsoil.

Collect mechanically. Treat the assimilated material according to the section on waste

disposal.

Clean up skills immediately and dispose of waste safety.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection.

Handling and storage

7.1. Precautions for safe handling

Handling: Observe instruction for use.

Advice on safe handling: No special precautionary measures are necessary.

Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands

and other exposed areas with mild soap and water before eating, drinking or smoking and

again when leaving work.

explosion:

Advice on protection against fire and No special measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container dry. Keep container tightly closed.

Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Further information on storage conditions: Recommended storage temperature: 2 °C - 30 °C (LabStrip U11 Plus, LabStrip U11 Plus GL

LabStrip U11 Plus MD) 2 °C - 25 °C (LabStrip U mALB/CREA,

LabStrip U12 mALB/CREA, LabStrip U12 mALB/CREA MD)

Protect against heat

Storage class (D):

Incompatible products: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

Laboratory Material. For professional use only.

Exposure controls, personal protection

8.1. **Control parameters**

Not applicable.



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8.2. Exposure controls

Appropriate Engineering Controls: Wash hands before breaks and at the end of the work.

Protective and hygiene measures: Wash hands before breaks and at the end of the work. When using do not eat or drink.

Personal Protective Equipment: Protective goggles. Gloves. Protective clothing.

Materials for Protective Clothing: Chemically resistant fabrics and materials

Hand protection: Tested protective gloves are to be worn: German Industry Norms (DIN) / European Norms

(EN): EN 374

Breakthrough times and swelling characteristics of the material must be taken into

consideration.

Eye protection: Eye protection: tightly sealed safety glasses (safety glasses are not necessary)

Skin and Body Protection:

Suitable protection of the body: Lab apron.
Footwear: Chemical resistant safety shoes.

Respiratory protection:

Other Information:

Respiratory protection not required.

When using do not eat, drink or smoke.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Solid, impregnated paper pads on plastic foil.

Colour: Depending on version.

Odour: Characteristic.

Odour threshold:
Physical properties:
pH:
No information available.
Not characterized.
Not appropriate.

Evaporation rate:

Melting point:

Freezing point:

Boiling point:

No information available.

Not determined.

Auto-ignition temperature:

Decomposition temperature:
Flammability (solid, gas):

Vapour pressure:
Relative vapour density at 20 °C:

No information available.
No information available.
No information available.

Solubility: Insoluble, but the reagent might be washed out of the test pad.

Relative density:
Partition coefficient:
No information available.
No information available.

n-octanol/water

Viscosity:

Explosive properties:

Oxidising properties:

Explosive limits:

No information available.

No information available.

No information available.

9.2. Other information

No additional information available.

10. Stability and reactivity

10.1. Reactivity

Hazardous reactions will not occur under normal conditions. (Not by usage according to the instructions.)

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

 $\label{thm:condition} \mbox{Hazardous polymerization will not occur under normal conditions}.$

10.4. Conditions to avoid

Decomposition possible after prolonged exposure to light. Direct sunlight. Extremely high or low temperature.



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10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

The product is not flammable. However, under fire conditions, decomposition may produce carbon dioxide, carbon monoxide and nitrogen oxides (NOx).

11. Toxicological information

11.1. Information on toxicological effects

No information available. Acute toxicity: Skin corrosion/irritation: No information available Serious eye damage/irritation: No information available. Respiratory or skin sensitization: No information available Germ cell mutagenicity: No information available. Carcinogenicity: No information available Reproductive toxicity: No information available. Specific target organ toxicity (single No information available.

exposure):

Specific target organ toxicity (repeated or

prolonged exposure): Aspiration hazards:

Symptoms/injuries after inhalation:

Symptoms/injuries after skin contact: Symptoms/injuries after eye contact: Symptoms/injuries after ingestion:

Chronic symptoms:

Specific effects in experiment on an animal:

Additional information on tests:

No information available.

No information available.

Not expected to present a significant inhalation hazard under anticipated conditions of

normal use.

May cause sensitization of susceptible persons by skin contact. May cause sensitization of susceptible persons by eye contact. If a large quantity has been ingested. May cause nausea or vomiting.

None expected under anticipated conditions of normal use.

No information available

The classification was undertaken in accordance with the calculation method governed by

the Preparations Directive (1999/45/EC)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No information available.

Other information 11.2.2.

No information available.

12. Ecological information

12.1. Toxicity

Hazards: Substance slightly hazardous to water and ground water.

No information available **Ecotoxicity:** LC50 fish 1: No information available. No information available. EC50 Daphnia 1: LC50 fish 2: No information available.

12.2. Persistence and degradability

Persistence and degradability: Product has not been tested. No information available. Not established.

12.3. Bioaccumulative potential

Bioaccumulative potential: Product has not been tested. No information available. Not established.

12.4. Mobility in soil

No additional information available.

12.5. Results of PBT and vPvB assessment

No additional information available.



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12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effect:

Other information: Avoid release to the environment.

The classification was undertaken in accordance with the calculation method governed by

the Preparations Directive (1999/45/EC).

Product has not been tested.

13. Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations:

Dispose of waste material in accordance with all local, regional, national and international

regulations.

Advice on disposal:

Other adverse effects:

Waste disposal according to official state regulations.

Waste disposal number of waste from residual/unused products (160506):

WASTES NOT OTHERWISE SPECIFIED IN THE LIST, gases in pressure containers and discarded chemicals, laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals.

Classified as hazardous waste.

Waste disposal number of used product (160506):

WASTES NOT OTHERWISE SPECIFIED IN THE LIST, gases in pressure containers and discarded chemicals, laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals.

Classified as hazardous waste.

Waste disposal number of contaminated packaging (160506):

WASTES NOT OTHERWISE SPECIFIED IN THE LIST, gases in pressure containers and discarded chemicals, laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals.

Classified as hazardous waste.

INADC

Contaminated packaging:

Water (with cleaning agent). Completely emptied packings can be re-cycled.

14.74

14. Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

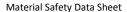
| ADR | RID | IMDG | IATA | ADN |
|-------------------------------|--|--|-----------------------------------|-----------------------------------|
| 14.1. UN numb | - | | | |
| 14.2. UN prope | r shipping name | Not applicable | Not applicable | Not applicable |
| 14.3. Transport | t hazard class(es) Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing g | roup Not applicable | Not applicable | Not applicable | Not applicable |
| 14.5. Environmental hazards | | | | |
| Dangerous for environment: NO | the Dangerous for t environment: NO | the Dangerous for the environment: NO Marine pollutant: NO | Dangerous for the environment: NO | Dangerous for the environment: NO |

14.6. Special precautions for user(s)

No additional information available.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.





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Land transport (RID/ADR):

Inland waterways transport:

Marine transport:

Air transport:

Other applicable information not restricted.

Notation for shipping indication: Diagnosticum.

Notes: Is not subject to current regulations for transportation of hazardous goods.

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions. Contains no substances on the REACH candidate list.

Contains no REACH Annex XIV substances.

15.1.2. National regulations

No additional information available.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

This product has no identification liability in accordance with EC Directives 67/548 and 88/379.

16. Other information

Data sources: According to Regulation (EU) No.1907/2006.

Abbreviations and acronyms

ADR Accord européen sur le transport des marchandises dangereuses par Route (European

Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG International Maritime Code for Dangerous Goods

IATA International Air Transport Association

GHS Globally Harmonized System of Classification and Labelling of Chemicals EINECS European Inventory of Existing Commercial Chemical Substances

ELINCS European List of Notified Chemical Substances

CAS Chemical Abstract Service LC50 Lethal concentration, 50%

LD50 Lethal dose, 50%

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

The information herein is believed to be correct as the data hereof but does purport to be all inclusive and shall be used only as a guide. 77 Elektronika Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product. The recipient of our product is responsible for ensuring that where applicable, existing laws and guidelines are observed.