

Trade name: UREA

Version: 01

Yürürlük Tarihi: 01.01.2024

Revizyon Tarihi: 00.00.0000

SDS-013-EN

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name**

Product Name: MEDITEST UREA

Product Code: 24UREA01-UN, 24UREA01-BT

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

In vitro diagnostic reagent for the quantitative determination of urea/urea nitrogen in human serum, plasma, and urine.

Uses advised against

No data available.

1.3 Details of the supplier of the safety data sheet**Address**

Medios Medikal Bilişim Danışmanlık Tic. Ltd. Şti.

Güzelevler Mahallesi Çınar Caddesi No:5 Yüreğir/Adana

Telefon: +903225020095

Email: medios@medios.com.trWebsite: www.medios.com.tr**1.4 Emergency telephone number**

For medical advice:

+90 533 461 3301

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification information**

This product does not meet the classification and labelling criteria given in the Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements**Supplemental label elements**

Biohazard

2.3 Other hazards

PBT assessment

No data available.

vPvB assessment

No data available.

SECTION 3: Composition/information on ingredients**3.1 Substances**

Not applicable. The product is not a substance.

3.2 Mixtures**Chemical characterization**

The product is an in vitro diagnostic enzymatic colorimetric reagent containing TRIS buffer (pH 7.8), α -ketoglutarate, urease, glutamate dehydrogenase (GLDH), and NADH. Urea in the sample is enzymatically hydrolyzed by urease to produce ammonium (NH_4^+) and carbon dioxide (CO_2). The resulting ammonium ions react with α -ketoglutarate in the presence of GLDH, simultaneously oxidizing NADH to NAD^+ . The rate of decrease in NADH concentration, measured photometrically, is proportional to the urea concentration in the sample.

Under normal conditions of use, the product is not classified as hazardous and does not contain any substances listed as dangerous under CLP Regulation (EC No 1272/2008).

Hazardous ingredients

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This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), annex II.

3.3 Other information

Do not inject or ingest.

SECTION 4: First aid measures**4.1 Description of first aid measures****General information**

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes and launder thoroughly before reusing.

After inhalation

Ensure supply of fresh air.

After skin contact

Rinse with plenty of water.

After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes).

After ingestion

Rinse the mouth thoroughly with water. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Carbon dioxide; Foam; Water spray jet; Extinguishing powder

Unsuitable extinguishing media

High power water jet

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO₂); Carbon monoxide (CO)

5.3 Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures****For non-emergency personnel**

Refer to protective measures listed in sections 7 and 8. Avoid contact with skin, eyes and clothing.

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

6.3 Methods and material for containment and cleaning up

Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When collected, handle material as described under the section heading "Disposal considerations".

6.4 Reference to other sections

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SECTION 7: Handling and storage**7.1 Precautions for safe handling****Advice on safe handling**

Risks inherent to handling the product must be minimised by applying the appropriate protective and preventive measures. Working processes should - so far as possible, according to the state of the art - be designed to rule out bodily contact or the release of hazardous substances.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapours. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities**Technical measures and storage conditions**

Keep container tightly closed. Store in refrigerator.

Recommended storage temperature

Value 2-8 °C

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

No parameters available for monitoring.

8.2 Exposure controls**Appropriate engineering controls**

No data available.

Personal protective equipment**Respiratory protection**

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Eye / face protection

Safety glasses (EN 166)

Hand protection

In case of intensive contact, wear protective gloves (EN 374). Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Other

Normal chemical work clothing.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****State of aggregation**

liquid

Form/Colour

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Clear Liquid

Colorless

Odour

No data available

pH value

No data available

Boiling point / boiling range

No data available

Melting point/freezing point

No data available

Decomposition temperature

No data available

Flash point

No data available

Ignition temperature

No data available

Flammability

No data available

Lower explosion limit

No data available

Upper explosion limit

No data available

Vapour pressure

No data available

Relative vapour density

No data available

Relative density

No data available

Density

No data available

Solubility in water

Reference temperature

20°C

Comments

soluble

Solubility

No data available

Partition coefficient n-octanol/water (log value)

No data available

Kinematic viscosity

No data available

Particle characteristics

No data available

9.2 Other information**Other information**

No data available.

SECTION 10: Stability and reactivity**10.1 Reactivity**

No data available.

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10.2 Chemical stability

Stable under recommended storage and handling conditions (See section 7).

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected when handling product according to its intended use.

10.4 Conditions to avoid

None, if handled according to intended use.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None, if handled according to intended use.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

No data available

Acute dermal toxicity

No data available

Acute inhalational toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Reproduction toxicity

No data available

Carcinogenicity

No data available

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Information on other hazards**Endocrine disrupting properties**

No data available.

Other information

No data available.

SECTION 12: Ecological information**12.1 Toxicity****Toxicity to fish (acute)**

No data available

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Toxicity to fish (chronic)

No data available

Toxicity to Daphnia (acute)

No data available

Toxicity to Daphnia (chronic)

No data available

Toxicity to algae (acute)

No data available

Toxicity to algae (chronic)

No data available

Bacteria 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**Results of PBT and vPvB assessment**

PBT assessment	No data available.
vPvB assessment	No data available.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

12.8 Other information**Other information**

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residues must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information**14.1 Transport ADR/RID/ADN**

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

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14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Maritime transport in bulk according to IMO instruments

Not relevant

SECTION 15: Regulatory information**Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)**

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances subject to restriction as listed in Annex XVII of the REACH regulation (EC) 1907/2006.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

15.1 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other information**Sources of key data used to compile the data sheet:**

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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