

Safety Data Sheet
According to Regulation (EC) No 1907/2006, Annex II,
Amended by COMMISSION REGULATION (EU) 2020/878,
Amended by COMMISSION DELEGATED REGULATION (EU) 2023/707,
According to REGULATION (EC) No 1272/2008

Urinalysis Control (Positive)

Version 1.0

Issue date: 22-05-2023

Revision date: 22-05-2023

SDS Record Number: CSSS-TCO-010-156026

Section 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Identification on the label/Trade name: Urinalysis Control (Positive)

Additional identification: Nanoform is NOT covered by this SDS.

UFI: N/A

Identification of the product: See section 3

Index Number: See section 3

REACH registration No.: See section 3

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

1.2.1 Identified uses:

Urinalysis control (referred to as Control) is used for quality control of urinalysis strips and analyzers. It can conduct quality control for 13 items of strips, such as Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leucocytes, Microalbumin, Creatinine and Ca.

1.2.2 Uses advised against:

Not available.

1.3 Details of the supplier of the safety data sheet:

Supplier(Only representative): -

Supplier(Manufacturer): DIRUI INDUSTRIAL CO., LTD.

Address: 95 Yunhe Street, New & High Tech. Development Zone Changchun, Jilin
130012 P.R. China

Contact person(E-mail): dirui@dirui.com.cn

Telephone: +86-431-85100409

Fax: +86-431-85172581

1.4 Emergency telephone Number:

+86-431-85100409

Only available during office hours (8:00a.m.-16:30p.m.)

Available outside office hours?

YES

☐

NO

☒

Section 2 Hazards identification

2.1 Classification of the substance or mixture:

2.1.1 Classification of the mixture:

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

REGULATION (EC) No 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

2.2 Label elements:

Product name: Urinalysis Control (Positive)

Version #: 1.0

Issue date: 22-05-2023.

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SDS EU

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Hazard pictogram(s): No hazard pictogram is used.

Signal word: No signal word is used.

Hazard statement(s): Not applicable.

Precautionary statement(s): Not applicable.

Supplemental Hazard information (EU) Not applicable.

2.3 Other hazards:

The mixture does not contain PBT/vPvB substance.

The mixture does not contain endocrine disruptor.

Section 3 Composition/information on ingredients

Substance/Mixture: Mixture

Ingredient(s):

Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification	Specific Concentration limits, M-Factors, Acute Toxicity Estimates (ATE)
water	N/A	7732-18-5	231-791-2	93.3%	Not Classified	N/A
Urea	N/A	57-13-6	200-315-5	2.00%	Not Classified	N/A
glucose	N/A	50-99-7	200-075-1	1.0%	Not Classified	N/A
ethyl acetoacetate	N/A	141-97-9	205-516-1	0.9%	Not Classified	N/A
albumin	N/A	9048-46-8	232-936-2	0.7%	H302	N/A
Sodium chloride	N/A	7647-14-5	231-598-3	0.5%	Not Classified	N/A
esterase	N/A	9016-18-6	232-773-7	0.5%	H334	N/A
sodium nitrite	N/A	7632-00-0	231-555-9	0.3%	H272 H301 H400	N/A
postassium dihydrogen phosphate	N/A	7778-77-0	231-913-4	0.2%	Not Classified	N/A
creatinine	N/A	60-27-5	200-466-7	0.2%	Not Classified	N/A
hemoglobin	N/A	9008-02-0	N/A	0.1%	Not available	N/A
Calcium chloride	N/A	10043-52-4	233-140-8	0.1%	H319	N/A
urobilinagen substitute	N/A	1076-74-0	214-066-5	0.1%	H315 H319 H335	N/A
bilirubin substitute	N/A	206659-00-9	N/A	0.1%	Not available	N/A

0.2% of the mixture consists of component (s) of unknown toxicity.

0.2% of components with unknown hazards to the aquatic environment.

Section 4 First aid measures

4.1 Description of first aid measures:

In all cases of doubt, or when symptoms persist, seek medical attention.

4.1.1 In case of inhalation:

None expected to require first aid measures. If breathed in, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical attention.

4.1.2 In case of skin contact:

None expected to require first aid measures. Wash thoroughly with soap and water. Get medical attention in the unlikely event that irritation persists.

4.1.3 In case of eyes contact:

None expected to require first aid measures. Flush with running water for at least 15 minutes. If irritation persists get medical attention.

4.1.4 In case of ingestion:

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 product is not classified as harmful to human health effect.

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

Symptomatic treatment.

Section 5 Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Use extinguishing agents appropriate for surrounding fire.

Unsuitable extinguishing media:

Not available.

5.2 Special hazards arising from the substance or mixture

No specific fire or explosion hazard. In case of fire, the following can be released: carbon monoxide, carbon dioxide, nitrogen oxides, phosphorus oxides, hydrogen chloride.

5.3 Advice for firefighters:

Wear self-contained breathing apparatus for fire fighting if necessary.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel:

Use personal protective equipment. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.1.2 For emergency responders:

Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.

6.2 Environmental precautions:

Avoid disposing into drainage/sewer system or directly into the aquatic environment.

6.3 Methods and material for containment and cleaning up:

Soak up with inert absorbent material. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections:

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

Section 7 Handling and storage

7.1 Precautions for safe handling:

7.1.1 Protective measures:

Ensure good ventilation/exhaustion at the workplace. Wash thoroughly after handling.

- 7.1.2 Advice on general occupational hygiene:
- 7.2 Conditions for safe storage, including any incompatibilities:
- 7.3 Specific end use(s):

Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

Refrigerated storage. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Not available.

Section 8 Exposure controls/personal protection

8.1 Control parameters:

8.1.1 Occupational exposure limits:

Country	Substance	EC No.	CAS No.	Occupational Exposure Limit Value (8-hour reference period)		Occupational Exposure Limit Value (15-minute reference period)		Notes
				ppm	mg/m ³	ppm	mg/m ³	
Latvia	Sodium chloride	231-598-3	7647-14-5	-	5	-	-	-
Romania	Ethyl acetoacetate	205-516-1	141-97-9	19	100	38	200	-
Latvia	Urea	200-315-5	57-13-6	-	10	-	-	-
Latvia	Calcium chloride	233-140-8	10043-52-4	-	2	-	-	-

8.1.2 Additional exposure limits under the conditions of use: Not available.

8.1.3 DNEL/DMEL and PNEC-Values: Not available.

8.2 Exposure controls:

8.2.1 Appropriate engineering controls: Use adequate ventilation to keep airborne concentrations low.

8.2.2 Individual protection measures, such as personal protective equipment:

Eye/face protection: No special requirements.

Skin protection

Hand protection: No special requirements. Wear gloves if necessary.

Body protection: No special requirements.

Respiratory protection: No special requirements.

Thermal hazards: Wear suitable protective clothing to prevent heat.

8.2.3 Environmental exposure controls: Avoid discharge into the environment. Dispose of rinse water in accordance with local and national regulations

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical state:	Liquid
Colour:	Not available
Odour:	Not available
Odour threshold:	Not available
pH:	Not available
Melting point/freezing point (°C):	801 °C(CAS#7647-14-5)
Boiling point or initial boiling point and boiling range (°C):	Not available
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (gas, liquid, solid):	Not available
Ignition temperature (°C):	Not available

Lower and upper explosion limit:	Not available
Vapour pressure (25°C):	Not available
Relative vapour density:	Not available
Relative Density (g/cm³):	2.16(25 °C, CAS#7647-14-5)
Bulk density (kg/m³):	Not available
Solubility in water (g/l, 20°C):	317 g/L(20 °C, CAS#7647-14-5)
Solubility in other polar and non-polar solvents (g/l, 20°C):	Not available
Partition coefficient n-octanol/water (log Po/w, 20°C):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Kinematic viscosity (mm²/s):	Not available
Particle characteristics:	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
9.2. Other information:	
Fat solubility(solvent– oil to be specified) etc:	Not available
Surface tension:	73.03 mN/m (23 °C, CAS#7647-14-5)
Dissociation constant in water(pKa):	Not available
Oxidation-reduction Potential:	Not available

Section 10 Stability and Reactivity

10.1 Reactivity:	The substance is stable under normal storage and handling conditions.
10.2 Chemical stability:	Stable at room temperature in closed containers under normal storage and handling conditions.
10.3 Possibility of hazardous reactions:	No dangerous reactions known.
10.4 Conditions to avoid:	Incompatible materials.
10.5 Incompatible materials:	Strong oxidizing agents.
10.6 Hazardous decomposition products:	Carbon monoxide, carbon dioxide, nitrogen oxides, phosphorus oxides, hydrogen chloride.

Section 11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Acute toxicity:	
ATE_{mix}(oral):	Not available
ATE_{mix}(inhalation):	Not available
ATE_{mix}(Dermal):	Not available
Sodium chloride (CAS#7647-14-5)	
LD50(Oral, Rat):	3550 mg/kg bw, male
LD50(Dermal, Rabbit):	> 10000 mg/kg bw
LC50(Inhalation, Rat):	> 42 mg/L, 1H
Skin corrosion/irritation:	Not classified
Serious eye damage/irritation:	Not classified
Respiratory or skin sensitization:	Not classified

Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
STOT- single exposure:	Not classified
STOT-repeated exposure:	Not classified
Aspiration hazard:	Not classified

11.2 Information on other hazards

Endocrine disrupting properties	The mixture does not contain endocrine disruptor.
Other information	Not applicable

Section 12 Ecological information

12.1 Toxicity:

Sodium chloride (CAS#7647-14-5)

Acute (short-term) toxicity:

LC50(96h, Fish): 5840 mg/L

LC50(48h, Crustacea): 874 mg/L

EC50(72h, Algae/aquatic plants): Not available

Chronic (long-term) toxicity:

NOEC(Fish): 252 mg/L

NOEC(Crustacea): 314 mg/L

NOEC(Algae/aquatic plants): Not available

12.2 Persistence and degradability: Not available.

12.3 Bioaccumulative potential: Not available.

12.4 Mobility in soil: Not available.

12.5 Results of PBT and vPvB assessment: The mixture does not contain PBT / vPvB substance.

12.6 Endocrine disrupting properties: The mixture does not contain endocrine disruptor.

12.7 Other adverse effects: Not available.

12.8 Additional information: Not available.

Section 13 Disposal considerations

13.1 Waste treatment methods: The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements.

Section 14 Transport Information

	Land transport (ADR/RID)	Inland waterways (ADN)	Sea transport (IMDG)	Air transport (ICAO/IATA)
14.1 UN number or ID number	Not regulated	Not regulated	Not regulated	Not regulated
14.2 UN proper shipping name	Not regulated	Not regulated	Not regulated	Not regulated
14.3 Transport hazard class(es)	Not regulated	Not regulated	Not regulated	Not regulated
14.4 Packing group	Not regulated	Not regulated	Not regulated	Not regulated

14.5 Environmental hazards	No	No	No	No
14.6 Special precautions for user	See section 2.2	See section 2.2	See section 2.2	See section 2.2
14.7 Maritime transport in bulk according to IMO instruments	Not regulated	Not regulated	Not regulated	Not regulated

Section 15 Regulatory information

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

Relevant information regarding authorization: Not applicable.

Relevant information regarding restriction: Not applicable.

Other EU regulations: Employment restrictions concerning young person must be observed. For use only by technically qualified individuals.

Other National regulations: Not applicable

15.2 Chemical Safety Assessment YES ☐ NO ☒

Section 16 Other information

16.1 Indication of changes:

Version 1.0 Amended by (EU) 2020/878

16.2 Abbreviations and acronyms:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: Code international maritime dangerous goods code

ICAO: International Civil Aviation Organization

IATA: International Air Transport Association

UFI: Unique Formula Identifier

LC50: median lethal concentration

EC50: The effective concentration of substance that causes 50% of the maximum response.

NOEC: No Observed Effect Concentration

DNEL: derived no-effect level

PNEC: predicted no-effect concentration

16.3 Key literature references and sources for data

ECHA Registered substances data

16.4 Training instructions:

Not applicable.

16.5 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

16.6 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

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