

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

FE Control II Positive Control

Version 1.0

Issue date: 06-04-2023

Revision date: 06-04-2023

SDS Record Number: CSSS-TCO-010-155438

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

1.1 Product identifier:

Identification on the label/Trade name: FE Control II Positive Control
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:

This product is used for QC of test process of Urine Sediment Analyzer, FUS Series Urinalysis Hybrid and MUS Series Urinalysis System.

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:

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

Product name: FE Control II Positive Control

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SDS EU

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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) |
|---------------|---|------------------|-----------|-----------|---------------|----------------|--|
| level 1 | Water | N/A | 7732-18-5 | 231-791-2 | 99.6780% | Not Classified | N/A |
| | Disodium Hydrogen Phosphate Dodecahydrate | N/A | 7558-79-4 | 231-448-7 | 0.2400% | Not Classified | N/A |
| | Triton X-100 | N/A | 9002-93-1 | N/A | 0.0500% | H302 H315 H319 | N/A |
| | Proclin 300 | N/A | N/A | N/A | 0.0300% | Not available | N/A |
| | Red blood cell | N/A | N/A | N/A | 0.0020% | Not available | N/A |
| level 2 | Water | N/A | 7732-18-5 | 231-791-2 | 99.6760% | Not Classified | N/A |
| | Disodium Hydrogen Phosphate Dodecahydrate | N/A | 7558-79-4 | 231-448-7 | 0.2400% | Not Classified | N/A |
| | Triton X-100 | N/A | 9002-93-1 | N/A | 0.0500% | H302 H315 H319 | N/A |
| | Proclin 300 | N/A | N/A | N/A | 0.0300% | Not available | N/A |
| | Red blood cell | N/A | N/A | N/A | 0.0040% | Not available | N/A |
| level 3 | Water | N/A | 7732-18-5 | 231-791-2 | 99.6715% | Not Classified | N/A |
| | Disodium Hydrogen Phosphate Dodecahydrate | N/A | 7558-79-4 | 231-448-7 | 0.2400% | Not Classified | N/A |
| | Triton X-100 | N/A | 9002-93-1 | N/A | 0.0500% | H302 H315 H319 | N/A |
| | Proclin 300 | N/A | N/A | N/A | 0.0300% | Not available | N/A |
| | Red blood cell | N/A | N/A | N/A | 0.0085% | Not available | N/A |

0.0300-0.0385% of the mixture consists of component (s) of unknown toxicity.
0.0300-0.0385% 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 oxides, phosphorus oxide.

5.3 Advice for firefighters:

In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. Wear chemical resistant oversuit. Cool containers / tanks with water spray.

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:

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

7.2 Conditions for safe storage, including any incompatibilities:

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.

7.3 Specific end use(s):

Not available.

Section 8 Exposure controls/personal protection

8.1 Control parameters:

8.1.1 Occupational exposure limits:

Not available.

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):

> 723 K(CAS#7558-79-4)

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/cm ³): | 2.07 (16 °C) (CAS#7558-79-4) |
| Bulk density (kg/m ³): | Not available |
| Solubility in water (g/l, 20°C): | Not available |
| 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 (mm ² /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: | Not available |
| Dissociation constant in water(pKa): | 2.16 (25 °C) (CAS#7558-79-4) |
| 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 oxides, phosphorus oxide. |

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 |
| Disodium Hydrogen Phosphate Dodecahydrate (CAS# 7558-79-4) | |
| LD50(Oral, Rat): | > 2000 mg/kg bw |
| LD50(Dermal, Rabbit): | > 2000 mg/kg bw |
| LC50(Inhalation, Rat): | > 0.83 mg/L 4h |
| 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:

Disodium Hydrogen Phosphate Dodecahydrate (CAS# 7558-79-4)

Acute (short-term) toxicity:

LC50(96h, Fish): > 100 mg/L

EC50(48h, Crustacea): > 100 mg/L

EC50(72h, Algae/aquatic plants): > 100 mg/L

Chronic (long-term) toxicity:

NOEC(Fish): Not available

NOEC(Crustacea): Not available

NOEC(Algae/aquatic plants): > 100 mg/L

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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