according to Regulation (EC) No. 453/2010

Creatinine PAP - Material number: 01 00400

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

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1.1 Product identifier

Name of product: Creatinine PAP Reagent

as part of the kits: 01 00400 XX XX XXXX (The positions X code different packages.)

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

Reagent for in-vitro diagnostics in human samples

1.3 Details of the supplier of the safety data sheet

Company name: DiaSystem Scandinavia AB

Street/POB-No.: Datorgatan 3
State/city/postal code: 561 33 Jönköping

Sweden

World Wide Web: http://www.diasystem.se

 Email:
 info@diasystem.se

 Telephone:
 +46 (0) 36 12 62 20

 Telefax:
 +46 (0) 36 18 77 30

Dept. responsible for information:

DiaSystem, Telephone: +46 (0) 36 12 62 20

1.4 Emergency telephone number

Giftinformationscentralen, Telephone +46 112

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified (for all components)

2.2 Label elements

Labelling (CLP)

Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified (for all components)

2.3 Other hazards

No risks worthy of mention.

Results of PBT and vPvB assessment:

No data available

3. Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

4. First aid measures

4.1 Description of first aid measures

In case of inhalation: Remove person to fresh air and keep comfortable for breathing.

Following skin contact: Wash skin with plenty of water.

After eye contact: Rinse eyes with water as a precaution.

After swallowing: Call a poison center or a doctor if you feel unwell.

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

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Treat symptomatically.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water spray. Dry powder. Foam. Carbon dioxide.

5.2 Special hazards arising from the substance or mixture

azardous decomposition products in case of fire. Toxic fumes may be released.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Do not attempt to take action without suitable protective equipment. Self-

contained breathing apparatus. Complete protective clothing.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Emergency procedures: Ventilate spillage area.

For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

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6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material.

Other information: Dispose of materials or solid residues at an authorized site.

6.4 Reference to other sections

For further information refer to section 13.

7. Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Store in a well-ventilated place. Keep cool.

7.3 Specific end use(s)

No additional information available

8. Exposure controls / Personal protection equipment

8.1 Control parameters

No additional information available

8.2 Exposure controls

Appropriate engineering controls: Ensure good ventilation of the work station.

Hand protection: Protective gloves Eye protection: Safety glasses

Skin and body protection: Wear suitable protective clothing

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Respiratory protection: In case of insufficient ventilation, wear suitable respiratory

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equipment

Environmental exposure controls: Avoid release to the environment.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Liquid

No data available Odour. No data available No data available Odour threshold: No data available pH value: No data available Melting point/freezing point: No data available Initial boiling point and boiling range: not combustible Flash point/flash point range: No data available Evaporation rate: No data available Flammability: No data available Explosion limits: No data available Vapour pressure: Vapour density: No data available No data available Density: No data available Water solubility: No data available Partition coefficient: n-octanol/water: No data available Auto-ignition temperature: No data available Decomposition temperature: Viscosity, kinematic: No data available No data available Explosive properties: No data available Oxidizing characteristics:

9.2 Other information

Additional information: No data available

10. Stability and reactivity

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Product is stable under normal storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5 Incompatible materials

No additional information available

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

11.1 Information on toxicological effects

Toxicological effects:

Acute toxicity (oral): Lack of data.
Acute toxicity (dermal): Lack of data.
Acute toxicity (inhalative): Lack of data.
Skin corrosion/irritation: Lack of data.
Serious eye damage/irritation: Lack of data.
Sensitisation to the respiratory tract: Lack of data.

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Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data. Reproductive toxicity: Lack of data. Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

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Aspiration hazard: Lack of data.

12. Ecological information

12.1 Toxicity Further details:

No data available

12.2. Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

13. Disposal considerations

13.1 Waste treatment method

Dispose of contents/container in accordance with licensed collector's sorting instructions.

14. Transport information

14.1 UN number

ADR/RID, IMDG, IATA-DGR: not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR: Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR: not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR: not applicable

14.5 Environmental hazards

Dangerous for the environment: NO

Marine pollutant: no

Other information: No supplementary information available

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No data available

15. Other information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU-Regulations

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

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National regulations

Germany

VwVwS Annex reference: Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4) 12th Ordinance Implementing the Federal Immission: Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance) Control Act - 12.BlmSchV

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Netherlands

SZW-lijst van kankerverwekkende stiffen: None of the components are listed

SZW-lijst van mutagene stiffen: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding: None of the components are listed NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid: None of the components are listed NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling: None of the components are listed

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

16. Other information

Further information

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SDS EU with CLP

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

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