according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2015/830

UniLab N - Material number: 07 00123

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

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1.1 Product identifier

Name of product: UniLab N

part of the kits 07 00123 XX XX XXX (The positions X code different packages.)

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

General use: 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
+46 (0) 36 12 62 20

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 EC regulation 1272/2008 (CLP)

This mixture is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements: not applicable
Precautionary Statements: not applicable

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

Chemical characterisation: lyophilisate

Additional information: Preparation does not contain dangerous substances above limits that need to be mentioned in this section

according to applicable EU-legislation.

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4. First aid measures

4.1 Description of first aid measures

In case of inhalation: Move victim to fresh air. Seek medical treatment in case of troubles.

Following skin contact: After contact with skin, wash immediately with soap and plenty of water. In case of skin reactions, consult

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a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of

troubles or persistent symptoms, consult an opthalmologist.

After swallowing: Rinse mouth immediately and drink plenty of water.

Seek medical attention. Do not induce vomiting without medical assistance.

4.2 Description of first aid measures

No data available

4.3 Description of first aid measures

Treat symptomatically.

5. Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surrounding.

5.2 Special hazards arising from the substance or mixture:

Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3 Advice for firefighters:

Special protective equipment for firefighters:

Wear a self-contained breathing apparatus

Additional information: Hazchem-Code: -

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment. Avoid contact with the substance. Provide adequate ventilation.

6.2 Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal. Clean the contaminated area with: chlorine-based bleaching agents (5%-solution) and water.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

7. Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Do

not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly

cleaned.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from light. Keep sterile

7.3 Conditions for safe storage, including any incompatibilities

No information available.

8. Exposure controls / Personal protection equipment

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

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according to regulation (20) not 2507/2000 (REPORT) and regulation (20)

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8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Provide adequate ventilation.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber-Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Lab coat.
General protection and hygiene measures:

Take off contaminated clothing and wash it before reuse. Do not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. Safety shower and eye wash station should be easily accessible to the work area.

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9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Physical state at 20 °C and 101.3 kPa: solid

Form: lyophilisate

Odour: odourless

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

9.2 Information on basic physical and chemical properties

Additional information: No data available

10. Stability and reactivity

10.1 Reactivity refer to 10.3

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 Keep away from heat.10.5 Incompatible materials strong acids and alkalis

10.6 Hazardous decomposition products

Fires in the immediate vicinity may cause the development of dangerous vapours.

Thermal decomposition: No data available

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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.

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:

General information: Do not allow to enter into ground-water, surface water or drains.

13. Disposal considerations

13.1 Waste treatment methods:

Product Waste key number: 18 01 04 = Wastes from natal care, diagnosis, treatment or prevention of disease in humans

Recommendation: Special waste. Dispose of waste according to applicable legislation.

Contaminated packaging

Waste key number: 15 01 06 = Mixed packaging of glass and plastic.

Recommendation: Dispose of waste according to applicable legislation. Non-contaminated packages may be

recycled.

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

Marine pollutant: no

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14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

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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

National regulations - Great Britain

Hazchem-Code: No data available

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

16. Other information

Further information

Reason of change: General revision (Regulation (EU) No 2015/830)

Date of first version: 2019-11-01

Department issuing data sheet

Contact person: see section 1: Department responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations). The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

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