

EU SAFETY DATA SHEET

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

UniCal CC - Material number: 06 00122

1. Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Name of product: UniCal CC
as part of the kits: 06 00122 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
For professional use only

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 126220

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 characterization: lyophilisate
Hazardous ingredients: 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 a physician.
After eye contact:	Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Induce vomiting. Seek medical attention.

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

Treat symptomatically.

5. Firefighting measures**5.1 Extinguishing media**

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

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 self-contained breathing apparatus..

Additional information: Hazchem-Code: -

6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Wear appropriate protective equipment. Avoid contact with the substance. Do not inhale 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. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Safety shower and eye wash station should be easily accessible to the work area.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep container in a well-ventilated place. Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from light. Keep sterile

7.3 Specific end use(s)

No information available.

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8. Exposure controls / Personal protection equipment**8.1 Control parameters**

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

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: Wear suitable protective clothing

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.

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

Colour: white

Odour: No data available

Odour threshold: No data available

pH value: not applicable

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point/flash point range: Not combustible

Evaporation rate: No data available

Flammability: No data available

Explosion limits: No data available

Vapour pressure: No data available

Vapour density: 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: No data available

Viscosity, kinematic: No data available

Explosive properties: No data available

Oxidizing characteristics: No data available

9.2 Other information

Additional information: No data available

10. Stability and reactivity**10.1 Reactivity**

refer to 10.3.

10.2 Chemical stability

No hazardous reactions known.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

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10.4 Conditions to avoid

Protect against heat /sun rays.

10.5 Incompatible materials

Strong acids and alkalis

10.6 Hazardous decomposition products

No decomposition when used properly.

Thermal decomposition:

No data available

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.
- 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 16 05 06* = Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals.

* = Evidence for disposal must be provided.

Recommendation: Special waste. Waste disposal according to official state regulations.

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.

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14.1 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: not applicable

IMDG: not applicable

IATA-DGR: not applicable

14.4 Packing group

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

14.5 Environmental hazards

Marine pollutant: no

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. Regulatory 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 mixture a chemical safety assessment is not required.

16. Other information**Further information**

Reason of change: General revision

Date of first version: 2011-07-01

Department issuing data sheet

Contact person: see section 1: Dept. 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.