

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: TruCal UIBC

As part of the kits:
1 1920 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
For professional use only.

1.3 Details of the supplier of the safety data sheet

Company name: DiaSys Diagnostic Systems GmbH

Street/POB-No.: Alte Strasse 9

Postal Code, city: DE-65558 Holzheim

WWW: <http://www.diasys.de>

E-mail: mail@diasys.de

Telephone: +49 (0) 6432-9146-0

Telefax: +49 (0) 6432-9146-32

Department responsible for information:

Corporate headquarters, Telephone: +49 (0) 6432-9146-0, Email: mail@diasys.de

1.4 Emergency telephone number

Infraserv, Telephone: +49 (0) 69-305-6418

SECTION 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.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable legislation.

Contains Sodium azide (0,95 g/L) as preservative.

SECTION 4: First aid measures

4.1 Description of first aid measures

- In case of inhalation: Move victim to fresh air. If you feel unwell, seek medical advice.
- Following skin contact: Change contaminated clothing.
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 thoroughly with water. Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- In case of ingestion: May be harmful if swallowed.
After contact with skin: May cause irritations.
After eye contact: May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically.

SECTION 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: Do not allow fire water to penetrate into surface or ground water.

SECTION 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

- Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance.

6.4 Reference to other sections

- Refer additionally to section 8 and 13.

SECTION 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. Do not freeze.
Protect from light. Keep sterile.

Hints on joint storage: Do not store together with: strong acids, alkalis.
Keep away from food, drink and animal feedingstuffs.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

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: If vapours form, use respiratory protection.
Use filter type ABEK according to EN 14387.

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: Avoid contact with skin and eyes. Change contaminated clothing. Wash hands before breaks and after work.
Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa: liquid

Colour: yellowish up to brown, clear up to opalescent

Odour: no characteristic odour

Odour threshold: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flammability: No data available

Upper/lower flammability or explosive limits: No data available

| | |
|-----------------------------------------|----------------------------|
| Flash point/flash point range: | not combustible |
| Decomposition temperature: | No data available |
| pH: | at 20 °C: 7,10 - 7,25 |
| Viscosity, kinematic: | No data available |
| Water solubility: | completely miscible |
| Partition coefficient: n-octanol/water: | No data available |
| Vapour pressure: | No data available |
| Density: | at 20 °C: 1,01 - 1,06 g/mL |
| Vapour density: | No data available |
| Particle characteristics: | Not applicable |

9.2 Other information

| | |
|----------------------------|-------------------|
| Explosive properties: | No data available |
| Oxidizing characteristics: | No data available |
| Auto-ignition temperature: | No data available |
| Evaporation rate: | No data available |
| Additional information: | No data available |

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Strong acids and alkalis

10.6 Hazardous decomposition products

No decomposition when used properly.

| | |
|------------------------|-------------------|
| Thermal decomposition: | No data available |
|------------------------|-------------------|

SECTION 11: Toxicological information

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

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.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: Contains Sodium azide (0,95 g/L):
After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

Symptoms

In case of ingestion: May be harmful if swallowed.
After contact with skin: May cause irritations.
After eye contact: May cause irritations.

SECTION 12: Ecological information

12.1 Toxicity

Water Hazard Class: 1 = slightly hazardous to water

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 Endocrine disrupting properties

No data available

12.7 Other adverse effects

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

SECTION 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. Dispose of waste according to applicable legislation.
Autoclave before disposal.

Package

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.

SECTION 14: Transport information

14.1 UN number or ID number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant - IMDG: no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

National regulations - Germany

Storage class: 12 = Non-combustible liquids

Water Hazard Class: 1 = slightly hazardous to water

Further regulations, limitations and legal requirements:
No data available

National regulations - EC member states

Further regulations, limitations and legal requirements:
No data available

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Reason of change: General revision

Date of first version: 26.1.2009

Department issuing data sheet: see section 1: Department responsible for information

Abbreviations and acronyms: ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
AS/NZS: Australian Standards/New Zealand Standards
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
CNS: Central Nervous System
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC: European Community
EN: European Standard
EQ: Excepted quantities
EU: European Union
IATA: International Air Transport Association
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative

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.