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

1.1 Product identifier

Trade name: TruLab Lp(a)

As part of the kits:
5 9830 XX XX XXX (Level 1)
5 9840 XX XX XXX (Level 2)
(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: lyophilisate

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

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

SECTION 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 opthalmologist.

After swallowing: Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Have victim drink large quantities of water, with active charcoal if possible. 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.

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

May form dangerous gases and vapours in case of fire.

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 suitable protective clothing. 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.

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. Protect from light.
Keep sterile.

Shelf life: 24 months

Storage class: 13 = Non-combustible solids

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: Dust mask or Respiratory protection mask with particulates filter according to EN 143.

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 or face protection shield.

Body protection: Wear suitable protective clothing. (protective apron, lab coat).

General protection and hygiene measures:

Take off contaminated clothing and wash it before reuse. 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.

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	solid Form: lyophilisate, powder
Colour:	weak yellowish
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:	Not applicable
Viscosity, kinematic:	No data available
Solubility:	No data available
Partition coefficient: n-octanol/water:	No data available

Vapour pressure:	No data available
Density:	No data available
Vapour density:	No data available
Particle characteristics:	No data available

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

Product is stable under normal storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

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

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.

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.

Package

Waste key number: 15 01 02 = Plastic packaging

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

Marine pollutant: 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: 13 = Non-combustible solids

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: 8.5.2008

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.