



# SAFETY DATA SHEET

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

Revision date: 29/4/2020  
Version: 16  
Language: en-GB,IE  
Date of print: 12/3/2021

## TruLab HbA1c liquid

Material number 5 9790/5 9800

Page: 1 of 8

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

#### 1.1 Product identifier

Trade name: TruLab HbA1c liquid  
As part of the kits:  
5 9790 XX XX XXX (Level 1)  
5 9800 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: 65558 Holzheim  
WWW: <http://www.diasys.de>  
E-mail: [mail@diasys.de](mailto: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](mailto: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

##### Special labelling

EUH208 Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.  
EUH210 Safety data sheet available on request.

#### 2.3 Other hazards

No risks worthy of mention.

Results of PBT and vPvB assessment:

No data available

**TruLab HbA1c liquid**

Material number 5 9790/5 9800

Page: 2 of 8

**SECTION 3: Composition / information on ingredients**

3.1 Substances: not applicable

**3.2 Mixtures**

Chemical characterisation: Aqueous solution

Hazardous ingredients:

Ingredient	Designation	Content	Classification
list no. 611-341-5 CAS 55965-84-9	Mixture of 5-chlorine-2-methyl- 2H-isothiazol-3-on and 2-methylen-2H- isothiazol-3-on (3:1)	< 0.0015 %	Acute Tox. 3; H301. Acute Tox. 2; H310. Acute Tox. 2; H330. Skin Corr. 1C; H314. Eye Dam. 1; H318. Skin Sens. 1A; H317. Aquatic Acute 1; H400 (M-factor = 100). Aquatic Chronic 1; H410 (M-factor = 100). (EUH071).

Full text of H- and EUH-statements: see section 16.

Additional information: Contains Sodium azide (0.18 g/L) as preservative.  
Contains Glycerol: The maximum workplace exposure limits are, where necessary, listed in section 8.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

In case of inhalation: Move victim to fresh air. In case of respiratory difficulties seek medical attention.

Following skin contact: Take off contaminated clothing and wash it before reuse. 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. Never give anything by mouth to an unconscious person. Seek medical attention.

**4.2 Most important symptoms and effects, both acute and delayed**

May cause allergic reactions in already sensitized persons.

**4.3 Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

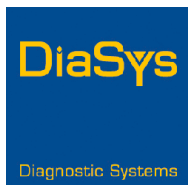
**SECTION 5: Firefighting measures****5.1 Extinguishing media**

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**

In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.



# SAFETY DATA SHEET

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

## TruLab HbA1c liquid

Material number 5 9790/5 9800

Revision date: 29/4/2020  
Version: 16  
Language: en-GB,IE  
Date of print: 12/3/2021

Page: 3 of 8

### 5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information:

Hazchem-Code: -

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 appropriate protective equipment. Provide adequate ventilation. Do not breathe vapours. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse.

### 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. Final cleaning.

### 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 breathe vapours. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

### 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 and alkalis.  
Keep away from food, drink and animal feedingstuffs.

### 7.3 Specific end use(s)

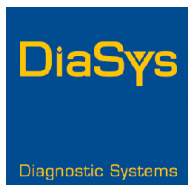
No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
56-81-5	Glycerol	Great Britain: WEL-TWA	10 mg/m <sup>3</sup>



# SAFETY DATA SHEET

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

Revision date: 29/4/2020  
Version: 16  
Language: en-GB,IE  
Date of print: 12/3/2021

## TruLab HbA1c liquid

Material number 5 9790/5 9800

Page: 4 of 8

## 8.2 Exposure controls

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

## Personal protection equipment

### Occupational exposure controls

- Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. Use combination filter type A/P according to EN 14387.
- Hand protection: Protective gloves according to EN 374.  
Glove material: natural latex or Nitrile rubber 0.5 mm.  
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:  
Do not breathe vapours. Take off contaminated clothing and wash it before reuse. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Have eye wash bottle or eye rinse ready at work place.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance: Physical state at 20 °C and 101.3 kPa: liquid  
Colour: red
- Odour: no characteristic odour
- Odour threshold: No data available
- pH: neutral
- 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: at 20 °C: 1,0084 g/mL
- 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

## 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 against heat /sun rays.

### 10.5 Incompatible materials

Strong acids and alkalis

### 10.6 Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

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: Based on available data, the classification criteria are not met.

Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

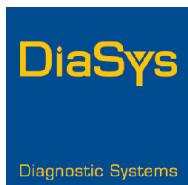
Reproductive toxicity: Lack of data.

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.



# SAFETY DATA SHEET

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

Revision date: 29/4/2020  
Version: 16  
Language: en-GB,IE  
Date of print: 12/3/2021

## TruLab HbA1c liquid

Material number 5 9790/5 9800

Page: 6 of 8

Other information: Contains Sodium azide (0.18 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

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.

## 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

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



# SAFETY DATA SHEET

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

## TruLab HbA1c liquid

Material number 5 9790/5 9800

Revision date: 29/4/2020  
Version: 16  
Language: en-GB,IE  
Date of print: 12/3/2021

Page: 7 of 8

### 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

### 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

## SECTION 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.

## SECTION 16: Other information

### Further information

Wording of the H-phrases under paragraph 2 and 3:

H301 = Toxic if swallowed.

H310 = Fatal in contact with skin.

H314 = Causes severe skin burns and eye damage.

H317 = May cause an allergic skin reaction.

H318 = Causes serious eye damage.

H330 = Fatal if inhaled.

H400 = Very toxic to aquatic life.

H410 = Very toxic to aquatic life with long lasting effects.

EUH071 = Corrosive to the respiratory tract.

EUH208 = Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.

EUH210 = Safety data sheet available on request.

## TruLab HbA1c liquid

Material number 5 9790/5 9800

Page: 8 of 8

### 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  
OEL: Occupational Exposure Limit Value  
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  
EU: European Union  
IATA: International Air Transport Association  
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  
M-factor: Multiplication factor  
OSHA: Occupational Safety and Health Administration  
PBT: Persistent, bioaccumulative and toxic  
PNEC: Predicted no-effect concentration  
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals  
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
TLV: Threshold Limit Value  
vPvB: Very persistent and very bioaccumulative  
WEL: Workplace Exposure Limit  
CNS: Central Nervous System

Reason of change: Changes in section 3: Composition / information on ingredients (CAS No. 55965-84-9)  
Changes in section 15: Regulatory information  
General revision

Date of first version: 30/9/2015

### Department issuing data sheet

Contact person: see section 1: Department responsible for information

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.

