

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

 Revision date:
 20/10/2016

 Version:
 7

 Language:
 en-GB,IE

 Date of print:
 12/3/2021

# HbA1c net FS Reagent R1

Material number 1 3348 R1 Page: 1 of 7

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

### 1.1 Product identifier

Trade name: HbA1c net FS Reagent R1

as part of the kits: 1 3348 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:
 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

Special labelling

Safety data sheet available on request.

### 2.3 Other hazards

No risks worthy of mention.

Results of PBT and vPvB assessment:

No data available



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

 Revision date:
 20/10/2016

 Version:
 7

 Language:
 en-GB,IE

 Date of print:
 12/3/2021

# HbA1c net FS Reagent R1

Material number 1 3348 R1 Page: 2 of 7

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

3.1 Substances: not applicable

#### 3.2 Mixtures

Chemical characterisation: Aqueous solution of inorganic salts and organic compounds.

Hazardous ingredients:

Ingredient	Designation	Content	Classification
CAS 25880-69-7	Maleic acid disodium salt hydrate	< 2 %	Skin Irrit. 2; H315. Eye Irrit. 2; H319. STOT SE 3; H335.

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

# **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. Remove residues with water. Seek medical attention if

irritation persists.

After eye contact: With eyelids open, wash out eyes for several minutes under flowing water. In case of

troubles or persistent symptoms, consult an opthalmologist.

After swallowing: Rinse mouth and drink large quantities of water. If you feel unwell, seek medical advice.

Never give anything by mouth to an unconscious person.

### 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

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

#### 5.3 Advice for firefighters

Special protective equipment for firefighters:

In case of surrounding fires: Wear self-contained breathing apparatus.

Additional information: Hazchem-Code: -

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



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

 Revision date:
 20/10/2016

 Version:
 7

 Language:
 en-GB,IE

 Date of print:
 12/3/2021

# HbA1c net FS Reagent R1

Material number 1 3348 R1 Page: 3 of 7

### **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Provide adequate ventilation.

Wear appropriate protective equipment.

### 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, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of 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: Avoid contact with skin and eyes.

Keep all containers, equipment and working place clean.

Wear appropriate protective equipment.

### 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.

# 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 adequate ventilation, and local exhaust as needed.

### 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



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

 Revision date:
 20/10/2016

 Version:
 7

 Language:
 en-GB,IE

 Date of print:
 12/3/2021

# HbA1c net FS Reagent R1

Material number 1 3348 R1 Page: 4 of 7

General protection and hygiene measures:

Change contaminated clothing.

Wash hands before breaks and after work. When using do not eat, drink or smoke.

# **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Appearance: Form: liquid

Colour: yellowish, brownish

Odour: weak

Odour threshold: No data available

pH: at 25 °C: 7.2

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 No data available Vapour pressure: Vapour density: No data available Density: at 20 °C: 1.0447 g/mL Water solubility: completely miscible 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

### 9.2 Other information

Additional information: No data available

# **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

Oxidizing characteristics:

refer to 10.3

#### 10.2 Chemical stability

Stable under recommended storage conditions.

No data available

#### 10.3 Possibility of hazardous reactions

No hazardous reactions known.

### 10.4 Conditions to avoid

Protect against heat /sun rays.



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

 Revision date:
 20/10/2016

 Version:
 7

 Language:
 en-GB,IE

 Date of print:
 12/3/2021

# HbA1c net FS Reagent R1

Material number 1 3348 R1 Page: 5 of 7

### 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

# **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: Based on available data, the classification criteria are not met. Serious eye damage/irritation: Based on available data, the classification criteria are not met.

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): Based on available data, the classification

criteria are not met.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

# **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



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

 Revision date:
 20/10/2016

 Version:
 7

 Language:
 en-GB,IE

 Date of print:
 12/3/2021

# HbA1c net FS Reagent R1

Material number 1 3348 R1 Page: 6 of 7

#### 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

### 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



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

 Revision date:
 20/10/2016

 Version:
 7

 Language:
 en-GB,IE

 Date of print:
 12/3/2021

# HbA1c net FS Reagent R1

Material number 1 3348 R1 Page: 7 of 7

# **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 substance a chemical safety assessment is not required.

# **SECTION 16: Other information**

#### **Further information**

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

H315 = Causes skin irritation.

H319 = Causes serious eye irritation. H335 = May cause respiratory irritation.

EUH210 = Safety data sheet available on request.

Reason of change: Changes in section 15: water hazard class

Date of first version: 17/1/2011

### 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.