



# SAFETY DATA SHEET

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

Revision date: 25/9/2021  
Version: 7.1  
Language: en-GB,IE  
Date of print: 6/9/2022

## HbA1c net FS Reagent R1

Material number 1 3348 R1

Page: 1 of 8

### 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](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

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

## HbA1c net FS Reagent R1

Material number 1 3348 R1

Page: 2 of 8

### 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 ophthalmologist.
- 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.

### 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

## HbA1c net FS Reagent R1

Material number 1 3348 R1

Page: 4 of 8

General protection and hygiene measures:

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

### Environmental exposure controls

Refer to "6.2 Environmental precautions".

## 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
Vapour pressure:	No data available
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
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.

## HbA1c net FS Reagent R1

Material number 1 3348 R1

Page: 5 of 8

### 10.4 Conditions to avoid

Protect against heat /sun rays.

### 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



# SAFETY DATA SHEET

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

Revision date: 25/9/2021  
Version: 7.1  
Language: en-GB,IE  
Date of print: 6/9/2022

## HbA1c net FS Reagent R1

Material number 1 3348 R1

Page: 6 of 8

### 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

### 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.



# SAFETY DATA SHEET

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

Revision date: 25/9/2021  
Version: 7.1  
Language: en-GB,IE  
Date of print: 6/9/2022

## HbA1c net FS Reagent R1

Material number 1 3348 R1

Page: 7 of 8

### 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

#### National regulations - EC member states

Further regulations, limitations and legal requirements:

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.



# SAFETY DATA SHEET

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

Revision date: 25/9/2021  
Version: 7.1  
Language: en-GB,IE  
Date of print: 6/9/2022

## HbA1c net FS Reagent R1

Material number 1 3348 R1

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  
AS/NZS: Australian Standards/New Zealand Standards  
CAS: Chemical Abstracts Service  
CFR: Code of Federal Regulations  
CLP: Classification, Labelling and Packaging  
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  
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals  
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
STOT SE: Specific target organ toxicity - single exposure  
TRGS: Technical Rules for Hazardous Substances  
vPvB: Very persistent and very bioaccumulative

Reason of change: General revision

Date of first version: 17/1/2011

### 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.