

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

Revision date: 6/2/2021 Version: 6.1 Language: en-GB,IE Date of print: 6/9/2022

HbA1c net FS Reagent R2

Material number 1 3348 R2 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 R2

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: 6/2/2021 Version: 6.1 Language: en-GB,IE Date of print: 6/9/2022

HbA1c net FS Reagent R2

Material number 1 3348 R2 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
EC No. 500-002-6 CAS 9002-92-0	Dodecan-1-ol, ethoxylated	< 2 %	Acute Tox. 4; H302. Eye Irrit. 2; H319.

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: Provide fresh air. If you feel unwell, seek medical advice.

Following skin contact: Take off contaminated clothing and wash it before reuse. Remove residues with 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 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

Liquid splashes can lead to irritations of the eyes.

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.



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Revision date: 6/2/2021 Version: en-GB IF Language: 6/9/2022 Date of print:

HbA1c net FS Reagent R2

Material number 1 3348 R2 Page: 3 of 8

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. 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, 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. Provide adequate ventilation, and local exhaust as needed. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.

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.

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: If vapours form, use respiratory protection.

Use combination filter type ABNO according to EN 14387.



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Revision date: 6/2/2021 Version: 6.1 Language: en-GB,IE Date of print: 6/9/2022

HbA1c net FS Reagent R2

Material number 1 3348 R2 Page: 4 of 8

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. Take off contaminated clothing and wash it before reuse. Wash hands before breaks and after work. When using do not eat, drink or smoke. 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

Appearance: Physical state at 20 °C and 101.3 kPa: liquid

Colour: greenish

No data available

Odour: weak

Odour threshold: No data available

pH: at 25 °C: 5.0 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: 1.0042 g/mL Water solubility: completely miscible

Auto-ignition temperature:

Decomposition temperature:

No data available

No data available

Viscosity, kinematic:

No data available

Explosive properties:

No data available

Oxidizing characteristics:

No data available

9.2 Other information

Partition coefficient: n-octanol/water:

Additional information: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to 10.3



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Revision date: 6/2/2021 Version: 6.1 Language: en-GB,IE Date of print: 6/9/2022

HbA1c net FS Reagent R2

Material number 1 3348 R2 Page: 5 of 8

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 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: Acute toxicity (oral): Based on available data, the classification criteria are not met.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

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): Lack of data. 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



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Revision date: 6/2/2021 Version: 6.1 Language: en-GB,IE Date of print: 6/9/2022

HbA1c net FS Reagent R2

Material number 1 3348 R2 Page: 6 of 8

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

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



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Revision date: 6/2/2021 Version: 6.1 Language: en-GB,IE Date of print: 6/9/2022

HbA1c net FS Reagent R2

Material number 1 3348 R2 Page: 7 of 8

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

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

Further information

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

H302 = Harmful if swallowed.

H319 = Causes serious eye irritation.

EUH210 = Safety data sheet available on request.



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Revision date: 6/2/2021 Version: 6.1 Language: en-GB,IE Date of print: 6/9/2022

HbA1c net FS Reagent R2

Material number 1 3348 R2 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

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.