



SAFETY DATA SHEET

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

Revision date: 13/2/2019
Version: 10
Language: en-GB,IE
Date of print: 12/3/2021

oneHbA1c FS Reagent R3

Material number 1 3329 R3

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

1.1 Product identifier

Trade name: oneHbA1c FS Reagent R3
As part of the kits: 1 3329 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

2.3 Other hazards

No risks worthy of mention.

Results of PBT and vPvB assessment:

No data available

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SECTION 3: Composition / information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution

Additional information: Preparation 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.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Move victim to fresh air. In case of accident or if you feel unwell, seek medical advice immediately. Keep at rest.

Following skin contact: Change contaminated clothing. 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. Subsequently consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Have victim drink large quantities of water, with active charcoal if possible. Immediately get medical attention. 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.

Water mist, extinguishing powder, foam, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Full water jet

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 positive pressure breathing apparatus and full firefighting protective clothing.

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Additional information: Hazchem-Code: -
Keep persons away and stay on the side facing the wind. Cool endangered containers with water jetspray. Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.
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

Provide adequate ventilation. Keep unprotected people away.
Avoid contact with skin and eyes. Wear appropriate protective equipment.
When using do not eat or drink.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Stop leak if safe to do so.
Small quantities: Collect spilled material using cloth and/or paper towels. Place in suitable container for disposal.
Larger quantities: 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.
Thoroughly clean surrounding area.

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 and eyes. Wear appropriate protective equipment.
Wash contaminated clothing before reuse.
Wash hands thoroughly after handling. When using do not eat or drink.

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 sunlight. Keep sterile.

Hints on joint storage: Do not store together with oxidizing agents or reducing agents.

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.

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8.2 Exposure controls

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

Personal protection equipment

Occupational exposure controls

- Respiratory protection: In case of inadequate ventilation wear respiratory protection.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.
- 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. Change contaminated clothing.
When using do not eat or drink. Wash hands before breaks and after work.
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: clear to slightly opalescent, colourless
- Odour: no characteristic odour
- Odour threshold: No data available
- pH: 8.2 (Reagent R1); 6.0 (Reagent R2)
- 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: No data available
- Water solubility: soluble
- 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 reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Protect from sunlight. Store in a cool dry place.

10.5 Incompatible materials

Oxidizing agents, reducing agents

10.6 Hazardous decomposition products

No decomposition when used properly.

Thermal decomposition: No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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.

Other information:

Contains Sodium azide (0.95 g/L) as preservative.

After resorption of toxic quantities: Headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.



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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 undiluted resp. in large quantities into surface water or into drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 05 09 = Discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

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



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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.

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SECTION 16: Other information

Further 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
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
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
vPvB: Very persistent and very bioaccumulative
CNS: Central Nervous System

Reason of change: General revision

Date of first version: 25/6/2008

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.

