

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

1.1 Product identifier

Trade name: HbA1c net Hemolyzing solution

As part of the kits: 1 4590 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: DE-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

EUH208

Contains N-Ethylmaleimide. May produce an allergic reaction.

EUH210

Safety data sheet available on request.

2.3 Other hazards

Can cause skin, eye and respiratory tract irritation.

A corrosive effect cannot be ruled out because of the pH value.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

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:

Identifiers	Designation Classification	Content
EC No. 239-002-3 CAS 14933-08-5	Dodecyldimethyl(3-sulphonatopropyl)ammonium Acute Tox. 4; H302. Acute Tox. 4; H312. Acute Tox. 4; H332. Skin Irrit. 2; H315. Eye Irrit. 2; H319. STOT SE 3; H335.	< 1,5 %
EC No. 204-892-4 CAS 128-53-0	N-Ethylmaleimide Acute Tox. 2; H300. Acute Tox. 3; H311. Skin Corr. 1B; H314. Skin Sens. 1; H317.	< 1 %

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 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

Can cause skin, eye and respiratory tract irritation. May cause allergic reactions in already sensitized persons.
A corrosive effect cannot be ruled out because of the pH value.

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:	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. Do not breathe vapours. Keep unprotected people away. 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. 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: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Wear appropriate protective equipment. Keep all containers, equipment and working place clean. Do not breathe vapours. 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. 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, alkalis.
Keep away from food, drink and animal feedingstuffs.

Storage class:

12 = Non-combustible liquids

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 filter type A (= against vapours of organic substances) according to EN 14387.

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. Do not breathe vapours. 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

Physical state at 20 °C and 101.3 kPa	liquid
Colour:	colourless up to weak cloudy
Odour:	weak up to odourless
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	not combustible
Decomposition temperature:	No data available
pH:	at 25 °C: 2,40 - 2,55
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20 °C: 1,0023 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available
Additional information:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Refer to subsection "Possibility of hazardous reactions".

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 hazard classes as defined in Regulation (EC) No 1272/2008

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): Based on available data, the classification criteria are not met.
ATEmix (calculated): > 5.000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.
ATEmix (calculated): > 5.000 mg/kg

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

Contains N-Ethylmaleimide. 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): Based on available data, the classification criteria are not met.

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

Aspiration hazard: Lack of data.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: Information about N-Ethylmaleimide:
LD50 Rat, oral: 25 mg/kg
LD50 Guinea pig, dermal: 500 mg/kg
Information about 2-Phenylethanol:
LD50 Rat, oral: 1.800 mg/kg
LD50 Rabbit, dermal: 790 mg/kg

Symptoms

A corrosive effect cannot be ruled out because of the pH value.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Harmful effects on water organisms by modification of pH-value.

Water Hazard Class: 2 = obviously hazardous to water

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 Endocrine disrupting properties

No data available

12.7 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 or ID number

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR:

Not restricted

14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.4 Packing group

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant - IMDG:

no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - Germany

Storage class: 12 = Non-combustible liquids
 Water Hazard Class: 2 = obviously hazardous to water
 Further regulations, limitations and legal requirements:
 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

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

H300 = Fatal if swallowed.
 H302 = Harmful if swallowed.
 H311 = Toxic in contact with skin.
 H312 = Harmful in contact with skin.
 H314 = Causes severe skin burns and eye damage.
 H315 = Causes skin irritation.
 H317 = May cause an allergic skin reaction.
 H319 = Causes serious eye irritation.
 H332 = Harmful if inhaled.
 H335 = May cause respiratory irritation.
 EUH208 = Contains N-Ethylmaleimide. May produce an allergic reaction.
 EUH210 = Safety data sheet available on request.

Reason of change: Changes in section 15: Water hazard class
 General revision

Date of first version: 7.2.2011

Department issuing data sheet: see section 1: Department responsible for information

Abbreviations and acronyms: Acute Tox.: Acute toxicity
 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
 Eye Irrit.: Eye irritation
 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
 LD50: Lethal dose 50%
 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
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 Skin Corr.: Skin corrosion
 Skin Irrit.: Skin irritation
 Skin Sens.: Skin sensitisation
 STOT SE: Specific target organ toxicity - single exposure
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2020/878

HbA1c net Hemolyzing solution

Material number 1 4590

Revision date: 20.12.2022

Version: 8.2

Replaces version: 8.1

Language: en-DE

Date of print: 11.1.2023

Page: 8 of 8

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.