

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

1.1 Product identifier

Trade name: Glucose Gluc-DH FS Reagent R2
As part of the kits: 1 2531 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)

Skin Sens. 1; H317 May cause an allergic skin reaction.

2.2 Label elements

Labelling (CLP)



Signal word: **Warning**
Hazard statements: H317 May cause an allergic skin reaction.
Precautionary statements: P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water/soap.

Special labelling

Text for labelling: Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1).

2.3 Other hazards

No risks worthy of mention.

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
REACH 01-2119457026-42-xxxx EC No. 201-069-1 CAS 5949-29-1	Citric acid monohydrate Eye Irrit. 2; H319. STOT SE 3; H335.	1 - 5 %
list no. 611-341-5 CAS 55965-84-9	Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1) Acute Tox. 3; H301. Acute Tox. 2; H310. Acute Tox. 2; H330. Skin Corr. 1C; H314. Eye Dam. 1; H318. Skin Sens. 1A; H317. Aquatic Acute 1; H400. Aquatic Chronic 1; H410. (EUH071). Specific concentration limits (SCL): Skin Corr. 1C; H314: $C \geq 0,6 \%$ / Skin Irrit. 2; H315: $0,06 \% \leq C < 0,6 \%$ / Eye Dam. 1; H318: $C \geq 0,6 \%$ / Eye Irrit. 2; H319: $0,06 \leq C < 0,6 \%$ Skin Sens. 1A; H317: $C \geq 0,0015 \%$ M-factors: Aquatic Acute 1: M = 100. Aquatic Chronic 1: M = 100.	0,0015 - 0,0025 %

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

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:	If medical advice is needed, have product container or label at hand.
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. After contact with skin, wash immediately with plenty of water. In case of skin irritation, 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 immediately and drink plenty of water. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

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.

Extinguishing media which must not be used for safety reasons:

Full water jet

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:

Wear self-contained breathing apparatus.

Additional information:

Do not allow water used to extinguish fire to enter drains, ground or waterways.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with the substance. Wear suitable protective clothing. Do not breathe vapours.

Provide adequate ventilation. If possible, eliminate leakage. 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. Final cleaning.

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. Wear appropriate protective equipment. Keep all containers, equipment and working place clean. Provide adequate ventilation, and local exhaust as needed. Do not breathe vapours. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. 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:

Store container tightly closed in a dry and cool place.

Storage temperature + 2 °C up to + 8 °C. Do not freeze. Protect from light. Keep sterile.

Hints on joint storage:

Do not store together with strong acids or 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 good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: If vapours form, use respiratory protection.
Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374.
Glove material: Nitrile rubber - Layer thickness 0,11 mm
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:
Do not breathe vapours. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls

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

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
Odour:	no characteristic odour
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: 4,5
Viscosity, kinematic:	No data available
Water solubility:	at 20 °C: completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20 °C: 1,014 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 dangerous reactions are 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): 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: Skin Sens. 1; H317 = May cause an allergic skin 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): Lack of data.

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

Symptoms

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Information about Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1):

Very toxic to aquatic life with long lasting effects.

Daphnia toxicity: EC50 Daphnia: 0,16 mg/L/48 h.

Fish toxicity: LC50 trout: 0,19 - 0,28 mg/L/96 h.

Water Hazard Class:

1 = slightly hazardous to water

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potentialPartition 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 effectsGeneral information: Do not allow to enter into ground-water, surface water or drains.
Contains biocide: Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and
2-methylen-2H-isothiazol-3-on (3:1).**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.

PackageWaste 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: 1 = slightly hazardous to water

Technical guidance air: 5.2.5

Information on working limitations:

Observe employment restrictions for young people.

Further regulations, limitations and legal requirements:

No data available

National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 3, 75

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:

H301 = Toxic if swallowed.

H310 = Fatal in contact with skin.

H314 = Causes severe skin burns and eye damage.

H317 = May cause an allergic skin reaction.

H318 = Causes serious eye damage.

H319 = Causes serious eye irritation.

H330 = Fatal if inhaled.

H335 = May cause respiratory irritation.

H400 = Very toxic to aquatic life.

H410 = Very toxic to aquatic life with long lasting effects.

EUH071 = Corrosive to the respiratory tract.

Reason of change: General revision

Date of first version: 21.2.2008

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

SAFETY DATA SHEET

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

Glucose Gluc-DH FS Reagent R2

Material number 1 2531 R2

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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
- Aquatic Acute: Hazardous to the aquatic environment - acute
- Aquatic Chronic: Hazardous to the aquatic environment - chronic
- 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
- EC50: Effective Concentration 50%
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Eye Dam.: Eye damage
- 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
- LC50: Median lethal concentration
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- M-factor: Multiplication factor
- 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
- Skin Corr.: Skin corrosion
- Skin Sens.: Skin sensitisation
- STOT SE: Specific target organ toxicity - single exposure
- TRGS: Technical Rules for Hazardous Substances
- vPvB: Very persistent and very bioaccumulative

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.