

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

1.1 Product identifier

Trade name: beta-Hydroxybutyrate FS Reagent R2

As part of the kits: 1 3701 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 Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and
2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.
EUH210 Safety data sheet available on request.

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
EC No. 200-659-6 CAS 67-56-1	Methanol Flam. Liq. 2; H225. Acute Tox. 3; H301. Acute Tox. 3; H311. Acute Tox. 3; H331. STOT SE 1; H370. Specific concentration limits (SCL): STOT SE 1; H370: $C \geq 10 \%$ / STOT SE 2; H371: $3 \% \leq C < 10 \%$	< 0,1 %
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 %

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 thoroughly with water. Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

May cause allergic reactions in already sensitized persons.
In case of eye contact: mild irritant

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 positive pressure breathing apparatus and full firefighting protective clothing.

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. 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. 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. 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 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

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
67-56-1	Methanol	Europe: IOELV: TWA	260 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		Germany: TRGS 900 Kurzzeit	260 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		Germany: TRGS 900 Langzeit	130 mg/m ³ ; 100 ppm (may be absorbed through the skin)

Biological limit values:

CAS No.	Designation Type	Limit value	Parameter	Sampling
67-56-1	Methanol Germany: TRGS 903, urine	15 mg/L	Methanol	at long term exposure, end of exposure or end of shift

8.2 Exposure controls

Provide adequate ventilation, and local exhaust as needed.

Personal protection equipment

Occupational exposure controls

Respiratory protection:	Provide adequate ventilation. Respiratory protection must be worn whenever the WEL levels have been exceeded.
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. Have eye wash bottle or eye rinse ready at work place. 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

Physical state at 20 °C and 101.3 kPa	liquid
Colour:	yellowish, clear
Odour:	no characteristic odour
Odour threshold:	No data available
Melting point/freezing point:	approx. 0 °C
Initial boiling point and boiling range:	approx. 100 °C
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	No data available
Decomposition temperature:	No data available
pH:	at 25 °C: 4,3
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: 1,012 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 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions with proper and specified storage and handling

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

Sensitisation to the respiratory tract: Lack of data.

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

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

Other information:

No data available



SAFETY DATA SHEET

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

beta-Hydroxybutyrate FS Reagent R2

Material number 1 3701 R2

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Replaces version: 10.0

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Date of print: 11.1.2023

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SECTION 12: Ecological information

12.1 Toxicity

Water Hazard Class: 1 = slightly 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: 1 = slightly 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:

H225 = Highly flammable liquid and vapour.

H301 = Toxic if swallowed.

H310 = Fatal in contact with skin.

H311 = Toxic in contact with skin.

H314 = Causes severe skin burns and eye damage.

H317 = May cause an allergic skin reaction.

H318 = Causes serious eye damage.

H330 = Fatal if inhaled.

H331 = Toxic if inhaled.

H370 = Causes damage to organs.

H400 = Very toxic to aquatic life.

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

EUH071 = Corrosive to the respiratory tract.

EUH208 = Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.

EUH210 = Safety data sheet available on request.

Reason of change: General revision

Date of first version: 5.3.2008

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

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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
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Eye Dam.: Eye damage
- Flam. Liq.: Flammable liquid
- 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
- M-factor: Multiplication factor
- OEL: Occupational Exposure Limit Value
- 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 Sens.: Skin sensitisation
- STOT SE: Specific target organ toxicity - single exposure
- TLV: Threshold Limit Value
- TRGS: Technical Rules for Hazardous Substances
- TSCA: Toxic Substance Control Act
- vPvB: Very persistent and very bioaccumulative
- WEL: Workplace Exposure Limit

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.