

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

### 1.1 Product identifier

Trade name: beta-Hydroxybutyrate 21 FS Reagent R1

As part of the kits:

1 3711 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](mailto: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](mailto: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)

Eye Irrit. 2; H319 Causes serious eye irritation.

### 2.2 Label elements

#### Labelling (CLP)



Signal word:

**Warning**

Hazard statements:

H319

Causes serious eye irritation.

Precautionary statements:

P264

Wash hands and face thoroughly after handling.

P280

Wear protective gloves/protective clothing/eye protection.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313

If eye irritation persists: Get medical advice/attention.

### 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

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 249-954-1 CAS 29915-38-6	3-(tris(Hydroxymethyl)methylamino)propane-1-sulphonic acid Acute Tox. 4; H302. Acute Tox. 4; H312.	< 3 %
EC No. 500-002-6 CAS 9002-92-0	Dodecan-1-ol, ethoxylated Acute Tox. 4; H302. Eye Dam. 1; H318. Aquatic Chronic 3; H412.	< 1,5 %

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

Additional information: Contains Sodium azide (0,95 g/L) as preservative.

**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: Move victim to fresh air. In case of respiratory difficulties seek medical attention.

Following skin contact: Take off contaminated clothing and wash it before reuse. After contact with skin, wash immediately with soap and plenty of 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. Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible. Never give anything by mouth to an unconscious person. Seek medical attention.

**4.2 Most important symptoms and effects, both acute and delayed**

Causes serious eye irritation.

**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**In the event of a fire, the following may be produced when the water evaporates: Sodium carbonate, nitrogen oxides (NO<sub>x</sub>), hydrogen chloride.**5.3 Advice for firefighters**

Special protective equipment for firefighters: 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 the substance. Wear appropriate protective equipment. Provide adequate ventilation. Keep unprotected people away. If possible, eliminate leakage. Do not breathe vapours. 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: Provide adequate ventilation, and local exhaust as needed. Wear appropriate protective equipment. Do not breathe vapours. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. 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.  
Protect from light. Keep sterile.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.  
Do not store together with strong acids or alkalis.

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: When aerosols and vapours form: Use combination filter type A/P 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. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place. Take off contaminated clothing and wash it before reuse.

**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
Odour:	like detergent
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:	No data available
Decomposition temperature:	No data available
pH:	at 25 °C: 8,5
Viscosity, kinematic:	No data available
Water solubility:	complete
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	1,0213 mg/L
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 hazardous reactions known.

**10.4 Conditions to avoid**

Protect from frost, heat and sunlight.

**10.5 Incompatible materials**

Strong acids, alkalis

## 10.6 Hazardous decomposition products

No decomposition when used properly.

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): > 2.000 mg/kg

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

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Eye Irrit. 2; H319 = Causes serious eye irritation.

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.

### 11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: Contains Sodium azide (0,95 g/L):  
After resorption of toxic quantities: Headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

Information about Dodecan-1-ol, ethoxylated:

LD50 Rat, oral: 1.000 mg/kg

LD50 human, oral: 500 - 5.000 mg/kg

## Symptoms

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

## 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



# SAFETY DATA SHEET

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

## beta-Hydroxybutyrate 21 FS Reagent R1

Material number 1 3711 R1

Revision date: 20.12.2022

Version: 4.1

Replaces version: 4.0

Language: en-DE

Date of print: 11.1.2023

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### 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, 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

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

Marine pollutant: 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:

The product is not subject to the Chemicals Prohibition Ordinance (ChemVerbotsV).

### National regulations - EC member states

Further regulations, limitations and legal requirements:

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

### 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:

H302 = Harmful if swallowed.

H312 = Harmful in contact with skin.

H318 = Causes serious eye damage.

H319 = Causes serious eye irritation.

H412 = Harmful to aquatic life with long lasting effects.

Reason of change: General revision

Date of first version: 20.5.2016

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
- 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
- CNS: Central Nervous System
- 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
- 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
- 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

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.