

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

### 1.1 Product identifier

Trade name: Total bile acids 21 FS Reagent R2  
As part of the kits: 1 2238 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)

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.

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.

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable 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: Provide fresh air. Seek medical treatment in case of troubles.
- Following skin contact: After contact with skin, wash immediately with soap and plenty of water. Take off contaminated clothing and wash it before reuse. 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. 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.

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.  
In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), sulphur oxides, carbon monoxide and carbon dioxide.

#### 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

Do not breathe vapours. Provide adequate ventilation. Wear appropriate protective equipment.  
Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse.

#### 6.2 Environmental precautions

Do not release large quantities into the surface water or into drains.

#### 6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal.  
Never return spills in original containers for re-use.

#### 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. Do not breathe vapours. Avoid contact with skin and eyes.  
Take off contaminated clothing and wash it before reuse. Wear appropriate protective equipment.  
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

### 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.

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.  
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. Do not get in eyes, on skin, or on clothing. 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.

### 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:	clear, colourless
Odour:	neutral
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

# SAFETY DATA SHEET

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

## Total bile acids 21 FS Reagent R2

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Decomposition temperature:	No data available
pH:	at 25 °C: 9
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: 1,0145 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

### 9.2 Other information

Explosive properties:	Product is not explosive.
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 reaction when handled and stored according to provisions.

### 10.4 Conditions to avoid

Protect from frost, heat and sunlight.

### 10.5 Incompatible materials

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:

- 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.

#### 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.

### 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 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: 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

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:

No data available

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

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### 15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

## SECTION 16: Other information

Reason of change: General revision

Date of first version: 11.12.2018

Department issuing data sheet: see section 1: Department responsible for 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  
EQ: Excepted quantities  
EU: European Union  
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  
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  
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.