

EU SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2015/830

Total Bile acids R2 - Material number: 01 00041

1. Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Name of product: Total Bile acids R2
as part of the kits: 01 00041 XX XX XXXX
(The positions X code different packages.)

1.2 Relevant identified uses of the substance or mixture and uses advised against

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: DiaSystem Scandinavia AB
Street/POB-No.: Datorgatan 3
State/city/postal code: 561 33 Jönköping
Sweden
World Wide Web: <http://www.diasystem.se>
Email: info@diasystem.se
Telephone: +46 (0) 36 12 62 20
Telefax: +46 (0) 36 18 77 30
Dept. responsible for information:
DiaSystem, Telephone: +46 (0)36 126220

1.4 Emergency telephone number

Giftinformationscentralen, Telephone +46 112

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

Results of PBT and vPvB assessment: No risks worthy of mention.
No data available

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3. Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution

Hazardous ingredients: Preparation 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

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: Change contaminated clothing. Remove residues with water. Seek medical attention if irritation persists.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. 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

No data available

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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. In case of fire may be liberated: carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

In case of surrounding fires: Wear self-contained breathing apparatus.

Additional information:

Hazchem-Code: -

Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Avoid contact with skin and eyes. Wear appropriate protective equipment. In enclosed areas: Provide fresh air.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or 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.

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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.

7.3 Specific end use(s)

No information available.

8. Exposure controls / Personal protection equipment**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: 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: Lab coat
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.

9. Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance: Physical state at 20 °C and 101.3 kPa: liquid
Colour: clear, colourless
Odour: neutral
Odour threshold: No data available
pH value: at 25 °C: 9
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point/flash point range: not combustible
Evaporation rate: No data available
Flammability: No data available
Explosion limits: No data available
Vapour pressure: No data available
Vapour density: No data available
Density: at 20 °C: 1.0145 g/mL
Water solubility: completely miscible
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity, kinematic: No data available
Explosive properties: Product is not explosive.
Oxidizing characteristics: No data available

9.2 Other information

Additional information: No data available

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10. Stability and reactivity**10.1 Reactivity**

Refer to subsection "Possibility of hazardous reactions".

10.2 Chemical stability

Product is stable under normal storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions are known.

10.4 Conditions to avoid

Protect against heat /sun rays.

10.5 Incompatible materials

Acids and alkalis

10.6 Hazardous decomposition products

No decomposition when used properly.

Thermal decomposition:

No data available

11. Toxicological information**11.1 Information on toxicological effects**

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.
May cause irritations. Irritation of the mucous membrane.
Specific target organ toxicity (repeated exposure): Lack of data.
Aspiration hazard: Lack of data.

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.

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 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

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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. Waste disposal according to official state regulations.

Contaminated packaging

Waste key number 15 01 02 = Plastic packaging.

Recommendation: Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

14.1 Transport information**14.1 UN 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

Marine pollutant: no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No data available

15. Other information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations - Great Britain**

Hazchem-Code: No data available

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

16. Other information**Further information**

Date of first version: 2020-02-01

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations). 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.