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

Total Bile acids R1- Material number: 01 00041

<u>1. Identification of the substance/mixture and of the company/undertaking</u>

1.1 Product identifier

Name of product:

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

Total Bile acids R1

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

No risks worthy of mention.

Results of PBT and vPvB assessment: No data available according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2015/830 Total Bile acids R1- Material number: 01 00041

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:			
Ingredient	Designation	Content	Classification
EC No. 611-341-5 CAS	Mixture of 5-Chloro-2-methyl-	< 0.0015 %	Acute Tox. 3; H301.
55965-84-9	2Hisothiazolin-3-one and 2-methyl-2H-		Acute Tox. 3; H311.
	isothiazol-3-one (3:1) [EC-No. 247-500-7 +		Acute Tox. 3; H331.
	220-239-6]		Skin Corr. 1B; H314.
			Skin Sens. 1; H317.
			Aquatic Acute 1; H400.
			Aquatic Chronic 1; H410

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

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 opthalmologist.
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

May be harmful if swallowed, in contact with skin or if inhaled. Irritating to eyes and skin. Irritation of the mucous membrane. Irritating to respiratory system.

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.

5.3 Advice for firefighters

Special protective equipment for firefighters:

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

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.

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6.4 Reference to other sections

Refer additionally to section 8 and 13.

7. Handling and storage

7.1 Precautions for safe handling

Provide adequate ventilation, and local exhaust as needed. Do not breathe vapours. Avoid contact with Advices on safe handling: 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. 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.

7.3 Specific end use(s)

No information available.

8. Exposure controls / Personal protection equipment

8.1 Control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Additional information:

Provide adequate ventilation, and local exhaust as needed.

Personal protection equipment

Occupational exposure controls

Respiratory protection:	If vapours form, use respiratory protection. Use filter type A (= against vapours of organic substances) 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		

General protection and hygiene measures

Change contaminated clothing. Wash hands before breaks and after work

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, yellowish
Odour:	neutral
Odour threshold:	No data available
pH value:	at 25 °C: 3.90
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: 1.0186 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:	No data available
Oxidizing characteristics:	No data available
9.2 Other information	

9.2 Other Information

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Additional information:

No data available

10. Stability and reactivity

10.1 Reactivity

Refer to subsection "Possilbility 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:

al 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: Based on available data, the classification criteria are not met. Contains Mixture of 5-Chloro-2-methyl-2H-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) [EC-No. 247-500-7 + 220-239-6]. 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.
- May cause irritations. Irritation of the mucous membrane.
- Specific target organ toxicity (repeated exposure): Lack of data.
- Aspiration hazard: Lack of data.

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

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12.6 Other adverse effects

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

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

Wording of the H-phrases under paragraph 2 and 3:

H301 = Toxic if swallowed.
H311 = Toxic in contact with skin.
H314 = Causes severe skin burns and eye damage.
H317 = May cause an allergic skin reaction.
H331 = Toxic if inhaled.
H400 = Very toxic to aquatic life.
H410 = Very toxic to aquatic life with long lasting effects.
EUH208 = Contains Mixture of 5-Chloro-2-methyl-2H-isothiazolin-3-one and
2-methyl-2H-isothiazol-3-one (3:1) [EC-No. 247-500-7 + 220-239-6]. May produce an allergic reaction

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Total Bile acids R1- Material number: 01 00041

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.