

EU SAFETY DATA SHEET

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

Bilirubin (Total) R2 - Material number: 01 00009**1. Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Name of product: Bilirubin (Total) Reagent R2
as part of the kits: 01 00009 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)**

Met. Corr. 1; H290 May be corrosive to metals.
Eye Irrit. 2; H319 Causes serious eye irritation.

2.2 Label elements**Labelling (CLP)**

Signal word: **Warning**

Hazard statements: H290 May be corrosive to metals

Precautionary statements: H319 Causes serious eye irritation.
P234 Keep only in original packaging.
P264 Wash hands and face thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338IF 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.
P390 Absorb spillage to prevent material damage.

2.3 Other hazards

A corrosive effect cannot be ruled out because of the pH value

Results of PBT and vPvB assessment:
No data available

EU SAFETY DATA SHEET

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

Bilirubin (Total) R2 - Material number: 01 00009

3. Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 500-002-6 CAS 9002-92-0	Dodecan-1-ol, ethoxylated	< 2.5 %	Acute Tox. 4; H302. Eye Dam. 1; H318.
EC No. 231-595-7 CAS 7647-01-0	Hydrochloric acid	< 1 %	Met. Corr. 1; H290 Skin Irrit. 1B; H314 STOT SE 3; H335

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. Seek medical treatment in case of troubles.

Following skin contact: Take off immediately all contaminated clothing. Remove residues with water. After contact with skin, wash immediately with plenty of water. Cover with sterile dressing material to protect against infection. Seek medical attention.

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 immediately and drink plenty of water. Do not induce vomiting. Do not try to neutralize. Seek medical attention. A corrosive effect cannot be ruled out because of the pH value.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation. Product can cause skin irritation because of the pH-value. May cause respiratory irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. Fire fighting measures**5.1 Extinguishing media**

Suitable extinguishing media: All extinguishing agents can be applied.

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_x), sulphur oxides, 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: 2X

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

Wear suitable protective clothing. Avoid contact with skin and eyes.

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.

EU SAFETY DATA SHEET

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

Bilirubin (Total) R2 - Material number: 01 00009**6.4 Reference to other sections**

Refer additionally to section 8 and 13.

7. Handling and storage**7.1 Precautions for safe handling**

Advices on safe handling: Provide adequate ventilation. Avoid contact with skin and eyes

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. Unsuitable materials: Metals

7.3 Specific end use(s)

No information available.

8. Exposure controls / Personal protection equipment**8.1 Control parameters**

Occupational exposure limit values:

Ingredient	Designation	Type	Limit value
7647-01-0	Hydrochloric acid	Europe: IOELV: STEL	15 mg/m ³ ; 10 ppm (Hydrogen chloride)
		Europe: IOELV: TWA	8 mg/m ³ ; 5 ppm (Hydrogen chloride)
		Great Britain: WEL-STEL	8 mg/m ³ ; 5 ppm (gas and aerosol mists)
		Great Britain: WEL-TWA	2 mg/m ³ ; 1 ppm (gas and aerosol mists) 1
		Ireland: 15 minutes	5 mg/m ³ ; 10 ppm
		Ireland: 8 hours	8 mg/m ³ ; 5 ppm

8.2 Exposure controls

Provide adequate ventilation, and local exhaust as needed.

Personal protection equipment**Occupational exposure controls**

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. Use filter type (E-P2/P3) according to EN 14387.

Hand protection: Protective gloves according to EN 374. Glove material: Nitrile rubber-Layer thickness: 0.11 mm. 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:

Change contaminated clothing. Wash hands before breaks and after work. Provide a conveniently located eye rinse station.

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: yellow up to reddish, clear

Odour: odourless

Odour threshold: No data available

pH value: at 25 °C: 0.90 - 0.95

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

EU SAFETY DATA SHEET

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

Bilirubin (Total) R2 - Material number: 01 00009

Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20 °C: 1.001 g/mL
Water solubility:	at 20 °C: 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

Additional information: No data available

10. Stability and reactivity**10.1 Reactivity**

May be corrosive to metals.

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

No data available.

10.5 Incompatible materials

Alkalis, metals

10.6 Hazardous decomposition productsIn case of fire may be liberated: Hydrogen chloride, Nitrogen oxides (NO_x), carbon monoxide and carbon dioxide.

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: 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): Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure): Lack of data.
Aspiration hazard: Lack of data.

Other information: A corrosive effect cannot be ruled out because of the pH value.

12. Ecological information**12.1 Toxicity**

Further details: Harmful effects on water organisms by modification of pH-value.

EU SAFETY DATA SHEET

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

Bilirubin (Total) R2 - Material number: 01 00009**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

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 150102 = 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: UN 3264

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR: UN 3264, CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Hydrochloric acid mixture)

14.3 Transport hazard class(es)

ADR/RID: Class 8, Code: C1

IMDG: Class 8, Subrisk -

IATA-DGR: Class 8

14.4 Packing group

ADR/RID, IMDG, IATA-DGR: III

14.5 Environmental hazards

Marine pollutant: no

14.6 Special precautions for user

Warning board: ADR/RID: Kemmler-number 80, UN number UN 3264

Hazard label: 8

Special provisions: 274

Limited quantities: 5 L

EQ: E1

Contaminated packaging - Instructions: P001 IBC03 LP01 R001

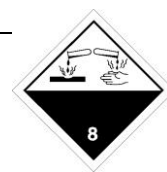
Special provisions for packing together: MP19

Portable tanks - Instructions: T7

Portable tanks - Special provisions: TP1 TP28

Tank coding: L4BN

Tunnel restriction code: E



EU SAFETY DATA SHEET

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

Bilirubin (Total) R2 - Material number: 01 00009

Sea transport (IMDG)

EmS: F-A, S-B
Special provisions: 223, 274
Limited quantities: 5 L
Excepted quantities: E1
Contaminated packaging - Instructions: P001, LP01
Contaminated packaging - Provisions: -
IBC - Instructions: IBC03
IBC - Provisions: -
Tank instructions - IMO: -
Tank instructions - UN: T7
Tank instructions - Provisions: TP1, TP28
Stowage and handling: Category A. SW2
Properties and observations: Causes burns to skin, eyes and mucous membranes.
Segregation group: 1

Air transport (IATA)

Hazard label: Corrosive
Excepted Quantity Code: E1
Passenger and Cargo Aircraft: Ltd.Qty.: Pack.Instr. Y841 - Max. Net Qty/Pkg. 1 L
Passenger and Cargo Aircraft: Pack.Instr. 852 - Max. Net Qty/Pkg. 5 L
Cargo Aircraft only: Pack.Instr. 856 - Max. Net Qty/Pkg. 60 L
Special provisions: A3 A803
Emergency Response Guide-Code (ERG): 8L

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: 2X
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:

H290 = May be corrosive to metals.
H302 = Harmful if swallowed.
H314 = Causes severe skin burns and eye damage.
H318 = Causes serious eye damage.
H319 = Causes serious eye irritation.
H335 = May cause respiratory irritation.

Reason of change: General revision (Regulation (EU) No 2015/830)
Date of first version: 2011-07-01

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.