

EU SAFETY DATA SHEET

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

Bilirubin (Total) R1 - 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 R1
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.
P390 Absorb spillage to prevent material damage.
P234 Keep only in original packaging.
P280 Wear protective gloves/protective clothing/eye protection/face 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.
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

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Bilirubin (Total) R1 - 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. 231-595-7 CAS 7647-01-0	Hydrochloric acid	1 - 5 %	Met. Corr. 1; H290. Skin Corr. 1B; H314. STOT SE 3; H335.
EC No. 200-311-3 CAS 57-09-0	Cetrimonium bromide	1 - 2 %	Acute Tox. 4; H302. Skin Irrit. 2; H315. Eye Dam. 1; H318. STOT SE 3; H335. STOT RE 2; H373. Aquatic Acute 1; H400.
EC No. CAS 9002-93-1	Octylphenoxypolyethoxyethanol (SVHC)	< 1 %	Acute Tox. 4; H302. Eye Dam. 1; H318. Aquatic Chronic 2; H411.
EC No. CAS 9036-19-5	Octylphenol, ethoxylated (SVHC)	< 1 %	Acute Tox. 4; H302. Eye Dam. 1; H318. Aquatic Chronic 2; H411.

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

Additional information: This mixture contains the following substances of very high concern (SVHC) which are subject to authorisation according to Annex XIV of REACH: Octylphenoxypolyethoxyethanol (EQC), Octylphenol, ethoxylated (EQC)

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 skin irritation. Causes serious eye irritation. May cause respiratory irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. Firefighting 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 (NOx), sulphur oxides, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

In case of surrounding fires: Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Hazchem-Code: 2X

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

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

Wear appropriate protective equipment. 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, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

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, and local exhaust as needed. Avoid contact with skin and eyes. Wear appropriate protective equipment.

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 Keep only in original container

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:

Take off immediately all contaminated clothing. Wash hands before breaks and after work. Provide a conveniently located eye rinse station.

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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:	colourless, clear
Odour:	odourless
Odour threshold:	No data available
pH value:	0.78 - 0.85
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:	1.0124 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 products

In case of fire may be liberated: Hydrogen chloride, hydrogen bromide (HBr), nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

Thermal decomposition:

No data available

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

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

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

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

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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.

Symptoms

In case of inhalation: May cause respiratory irritation.
After contact with skin: May cause irritations.
After eye contact: Causes serious eye irritation.

12. Ecological information**12.1 Toxicity**

Aquatic toxicity: Harmful effects on water organisms by modification of pH-value. Information about Cetrimonium bromide
Daphnia toxicity: EC50 Daphnia magna (Big water flea) 0.03 mg/L/48h Fish toxicity: LC50 Brachydanio rerio (zebra-fish) 0.3 mg/L/96h

12.2. Persistence and degradability

Further details: Information about Cetrimonium bromide Biodegradation: 100 %/28 d. Product is readily biodegradable.

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.

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Bilirubin (Total) R1 - Material number: 01 00009**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

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

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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.
H315 = Causes skin irritation.
H318 = Causes serious eye damage.
H319 = Causes serious eye irritation.
H335 = May cause respiratory irritation.
H373 = May cause damage to organs through prolonged or repeated exposure.
H400 = Very toxic to aquatic life.
H411 = Toxic to aquatic life with long lasting effects.

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.