

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

1.1 Product identifier

Trade name: Bilirubin Auto Total FS Reagent R1

As part of the kits: 1 0811 XX XX XXX
(The positions X code different packages.)

UFI: T300-P0FG-P003-GFP3

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

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

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)

Met. Corr. 1; H290	May be corrosive to metals.
Skin Irrit. 2; H315	Causes skin irritation.
Eye Irrit. 2; H319	Causes serious eye irritation.
Aquatic Acute 1; H400	Very toxic to aquatic life.
Aquatic Chronic 3; H412	Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (CLP)



Signal word:

Warning

Hazard statements:

H290	May be corrosive to metals.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements:	P234	Keep only in original packaging.
	P264	Wash hands and face thoroughly after handling.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection.
	P337+P313	If eye irritation persists: Get medical advice/attention.
	P391	Collect spillage.

2.3 Other hazards

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

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

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 231-595-7 CAS 7647-01-0	Hydrochloric acid Met. Corr. 1; H290. Skin Corr. 1B; H314. STOT SE 3; H335. Specific concentration limits (SCL): Skin Corr. 1B; H314: $C \geq 25\%$ / Skin Irrit. 2; H315: $10\% \leq C < 25\%$ / Eye Irrit. 2; H319: $10\% \leq C < 25\%$ / STOT SE 3; H335: $C \geq 10\%$	< 5 %
REACH 01-2119989160-35-xxxx EC No. 200-311-3 CAS 57-09-0	Cetrimonium bromide Acute Tox. 4; H302. Skin Irrit. 2; H315. Eye Dam. 1; H318. STOT SE 3; H335. STOT RE 2; H373. Aquatic Acute 1; H400. Aquatic Chronic 1; H410. Specific concentration limits (SCL): Skin Irrit. 2; H315: $C \geq 2,5\%$ M-factors: Aquatic Acute 1: M = 100. Aquatic Chronic 1: M = 1.	< 2,5 %

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

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:	If medical advice is needed, have product container or label at hand. First aider: Pay attention to self-protection!
In case of inhalation:	Provide fresh air. Seek medical aid in case of troubles.
Following skin contact:	After contact with skin, wash immediately with plenty of water. Take off contaminated clothing and wash it before reuse. 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. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently seek the immediate attention of an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Do not try to neutralize. Immediately get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation. Causes skin irritation.

A corrosive effect cannot be ruled out because of the pH value. May cause respiratory irritation.

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.

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: Hydrogen chloride (HCl), hydrogen bromide (HBr), nitrogen oxides (NO_x), 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:

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

Provide adequate ventilation. Do not breathe mist/vapours/spray. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.

Avoid contact with skin and eyes. Keep unprotected people away.

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. Final cleaning.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling:

Provide adequate ventilation, and local exhaust as needed. Do not breathe mist/vapours/spray. Avoid contact with skin and eyes. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. 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.

Unsuitable materials: Metals

Keep only in original container.

Hints on joint storage: Do not store together with alkalis.
Keep away from food, drink and animal feedingstuffs.

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

Occupational exposure limit values:

CAS No.	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)
		Germany: TRGS 900 Kurzzeit	6 mg/m ³ ; 4 ppm (Hydrogen chloride)
		Germany: TRGS 900 Langzeit	3 mg/m ³ ; 2 ppm (Hydrogen chloride)

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: Wear suitable protective clothing.

General protection and hygiene measures:
Avoid contact with skin and eyes. Wash hands before breaks and after work. Do not breathe mist/vapours/spray. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

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 to slightly opalescent, colourless to slightly yellowish
Odour:	no characteristic odour
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
Decomposition temperature:	No data available
pH:	0,8 - 0,9

Viscosity, kinematic:	No data available
Water solubility:	at 20 °C: completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	1,0124 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	No data available
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

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

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Alkalis, metals

10.6 Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition:	No data available
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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.
ATEmix (calculated): ATE > 5.000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.
ATEmix (calculated): ATE > 5.000 mg/kg

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Skin Irrit. 2; H315 = Causes skin irritation.

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.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: Information about Cetrimonium bromide:
LD50 Rat, oral: 465 mg/kg
LD50 Rabbit, dermal: 2.150 mg/kg

Symptoms

A corrosive effect cannot be ruled out because of the pH value. May cause respiratory irritation.
After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Very toxic to aquatic life with long lasting effects.
Information about Cetrimonium bromide:
Fish toxicity:
LC50 Danio rerio (zebrafish): 0,2 mg/L/96h (OECD 203)
Daphnia toxicity:
EC50 Daphnia magna (Big water flea): 0,026 mg/L/48h (OECD 202)
Algae toxicity:
EC50 Pseudokirchneriella subcapitata (green algae): 0,00411 mg/L/72h (OECD 201)

Water Hazard Class: 3 = highly hazardous to water

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: Special waste. 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:
UN 3264

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

ADR/RID, ADN: Class 8, Code: C1
IMDG: Class 8, Subrisk -
IATA-DGR: Class 8

14.4 Packing group

ADR/RID: III

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant - IMDG: yes

Marine pollutant - ADN: yes



14.6 Special precautions for user

Land transport (ADR/RID)

Warning board:	ADR/RID: Kemmler-number 80, UN number UN 3264
Hazard label:	8
Special Provisions:	274
Limited quantities:	5 L
EQ:	E1
Package - 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

Inland waterway craft (ADN)

Hazard label:	8
Special Provisions:	274
Limited quantities:	5 L
EQ:	E1
Transport permitted:	T
Equipment necessary:	PP - EP

Sea transport (IMDG)

EmS:	F-A, S-B
Special Provisions:	223 274
Limited quantities:	5 L
Excepted quantities:	E1
Package - Instructions:	P001, LP01
Package - Provisions:	-
IBC - Instructions:	IBC03
IBC - Provisions:	-
Tank instructions - IMO:	-
Tank instructions - UN:	T7
Tank instructions - Provisions:	TP1, TP28
Stowage and handling:	Category A. SW2
Segregation:	SG36 SG49
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 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
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Water Hazard Class: 3 = highly hazardous to water

Incident regulation: Richtlinie 2012/18/EU (Seveso III):
Umweltgefahren: Ziffer 1.3.1 = Code E1, Mengenschwelle 100 000kg / 200 000kg

Information on working limitations:
Observe employment restrictions for young people.

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:
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances
[Seveso-III-Directive] refer to Germany, 12. BImSchV
Use restriction according to REACH annex XVII, no.: 3, 75
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances
[Seveso-III-Directive]: E1

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other 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.
H410 = Very toxic to aquatic life with long lasting effects.

Reason of change: General revision

Date of first version: 30.10.2006

Department issuing data sheet: see section 1: Department responsible for information

SAFETY DATA SHEET

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

Bilirubin Auto Total FS Reagent R1

Material number 1 0811 R1

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Abbreviations and acronyms:

- Acute Tox.: Acute toxicity
- 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
- Aquatic Acute: Hazardous to the aquatic environment - acute
- Aquatic Chronic: Hazardous to the aquatic environment - chronic
- AS/NZS: Australian Standards/New Zealand Standards
- ATE: Acute toxicity estimate
- CAS: Chemical Abstracts Service
- CFR: Code of Federal Regulations
- CLP: Classification, Labelling and Packaging
- DMEL: Derived minimal effect level
- DNEL: Derived no-effect level
- EC: European Community
- EC50: Effective Concentration 50%
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Eye Dam.: Eye damage
- Eye Irrit.: Eye irritation
- 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
- LC50: Median lethal concentration
- LD50: Lethal dose 50%
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- Met. Corr.: Corrosive to metals
- M-factor: Multiplication factor
- OECD: Organisation for Economic Co-operation and Development
- OEL: Occupational Exposure Limit Value
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- Skin Corr.: Skin corrosion
- Skin Irrit.: Skin irritation
- STOT RE: Specific target organ toxicity - repeated exposure
- STOT SE: Specific target organ toxicity - single exposure
- TLV: Threshold Limit Value
- TRGS: Technical Rules for Hazardous Substances
- TSCA: Toxic Substance Control Act
- UN: United Nations
- vPvB: Very persistent and very bioaccumulative
- WEL: Workplace Exposure Limit

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.