

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

1.1 Product identifier

Trade name: Bilirubin Auto Direct FS Reagent R1
As part of the kits: 1 0821 XX XX XXX
(The positions X code different packages.)

UFI: N800-P0U9-9003-T4U7

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: 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.

2.2 Label elements

Labelling (CLP)



Signal word:

Warning

Hazard statements: H290 May be corrosive to metals.

Precautionary statements: P234 Keep only in original packaging.

P390 Absorb spillage to prevent material damage.

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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

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: aqueous solution

Hazardous ingredients:

| Ingredient | Designation | Content | Classification |
|--------------------------------------|------------------|---------|--|
| EC No. 226-218-8 CAS 5329-14-6 | Sulphamidic acid | < 1 % | Skin Irrit. 2; H315. Eye Irrit. 2; H319. Aquatic Chronic 3; H412. |

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

SECTION 4: First aid measures**4.1 Description of first aid measures**

| | |
|-------------------------|--|
| In case of inhalation: | Provide fresh air. Seek medical aid in case of troubles. |
| Following skin contact: | Take off contaminated clothing and wash it before reuse. 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. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently seek the immediate attention of an ophthalmologist. |
| After swallowing: | Never give anything by mouth to an unconscious person. Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Risk of perforation! Do not try to neutralize. Seek medical attention. |

4.2 Most important symptoms and effects, both acute and delayed

A corrosive effect cannot be ruled out because of the pH value. Can cause skin, eye and respiratory tract 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: Sulphur oxides, nitrogen oxides (NO_x).

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

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.

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

Advices 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 immediately all 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: Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide for good ventilation or exhaust system or work with completely self-contained equipment.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Use a breathing protection against vapours/aerosol.
Use filter type (B-P2) 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 immediately all 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

Appearance: Physical state at 20 °C and 101.3 kPa: liquid
Colour: colourless, clear

Odour: no characteristic odour

Odour threshold: No data available

pH: at 25 °C: 1.1

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

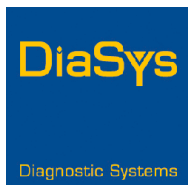
Vapour pressure: No data available

Vapour density: No data available

Density: at 20 °C: 1,0103 g/mL

Water solubility: at 20 °C: completely miscible

Partition coefficient: n-octanol/water: No data available



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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

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

Keep away from heat.

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

SECTION 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.
Specific target organ toxicity (repeated exposure): Lack of data.
Aspiration hazard: Lack of data.

Symptoms

A corrosive effect cannot be ruled out because of the pH value. Can cause skin, eye and respiratory tract irritation.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Harmful effects on water organisms by modification of pH-value.

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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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

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. (Sulphamidic 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

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



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

No data available

SECTION 15: Regulatory 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

National regulations - EC member states

Further regulations, limitations and legal requirements:
No data available

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.



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SECTION 16: Other information

Further information

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

- H290 = May be corrosive to metals.
- H315 = Causes skin irritation.
- H319 = Causes serious eye irritation.
- H412 = Harmful to aquatic life with long lasting effects.

Abbreviations and acronyms:

- 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
- AS/NZS: Australian Standards/New Zealand Standards
- 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
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- 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
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- 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
- TRGS: Technical Rules for Hazardous Substances
- UN: United Nations
- vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 1: Product Identification

Date of first version: 31/10/2006

Department issuing data sheet

Contact person: see section 1: Department responsible for information

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.