

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

### 1.1 Product identifier

Trade name: Alkaline Phosphatase FS DGKC Reagent R1  
As part of the kits: 1 0401 XX XX XXX  
(The positions X code different packages.)

### 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](mailto: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](mailto: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)

Skin Irrit. 2; H315 Causes skin irritation.  
Eye Dam. 1; H318 Causes serious eye damage.  
STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure.

### 2.2 Label elements

#### Labelling (CLP)



Signal word:

**Danger**

Hazard statements: H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H373 May cause damage to organs through prolonged or repeated exposure.

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Precautionary Statements:

- P260 Do not breathe vapours.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 IF ON SKIN: Wash with plenty of water/soap.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P310 Call a POISON CENTER/doctor if you feel unwell.

**Special labelling**

Text for labelling: Contains Diethanolamine.

**2.3 Other hazards**

No risks worthy of mention.

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 of inorganic salts and organic compounds.

Hazardous ingredients:

| Ingredient                          | Designation    | Content   | Classification   |
|-------------------------------------|----------------|-----------|--|
| EC No.<br>203-868-0<br>CAS 111-42-2 | Diethanolamine | 10 - 20 % | Acute Tox. 4; H302. Skin Irrit. 2; H315.<br>Eye Dam. 1; H318. STOT RE 2; H373.<br>Aquatic Chronic 3; H412. |
| EC No.<br>200-659-6<br>CAS 67-56-1  | Methanol       | < 0.5 %   | Flam. Liq. 2; H225. Acute Tox. 3; H301.<br>Acute Tox. 3; H311. Acute Tox. 3; H331.<br>STOT SE 1; H370.     |

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. If you feel unwell, seek medical advice.  
Following skin contact: Change contaminated clothing. After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician.  
After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.  
After swallowing: Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not unconscious. Immediately get medical attention.

**4.2 Most important symptoms and effects, both acute and delayed**

May cause damage to organs through prolonged or repeated exposure. Causes skin irritation. Causes serious eye damage.

**4.3 Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

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### 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: Nitrogen oxides (NO<sub>x</sub>), carbon monoxide and carbon dioxide.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information:

Hazchem-Code: -

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

Avoid contact with the substance. Wear suitable protective clothing. Do not breathe vapours. Provide adequate ventilation.

#### 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.

#### 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 vapours. Avoid contact with skin and eyes. Wear appropriate protective equipment.

Keep all containers, equipment and working place clean.

#### 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. Protect from light. Keep sterile.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

#### 7.3 Specific end use(s)

No information available.

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**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

Occupational exposure limit values:

| CAS No.  | Designation    | Type  | Limit value  |
|----------|----------------|---|--|
| 111-42-2 | Diethanolamine | Great Britain: MEL/OES-TWA<br>Ireland: 8 hours  | 13 mg/m <sup>3</sup> ; 3 ppm<br>1 mg/m <sup>3</sup> ; 0.2 ppm<br>(inhalable fraction and vapour)   |
| 67-56-1  | Methanol       | Europe: IOELV: TWA<br>Great Britain: WEL-STEL<br>Great Britain: WEL-TWA<br>Ireland: 8 hours | 260 mg/m <sup>3</sup> ; 200 ppm<br>(may be absorbed through the skin)<br>333 mg/m <sup>3</sup> ; 250 ppm<br>(may be absorbed through the skin)<br>266 mg/m <sup>3</sup> ; 200 ppm<br>(may be absorbed through the skin)<br>260 mg/m <sup>3</sup> ; 200 ppm<br>(may be absorbed through the skin) |

**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 A-(P2) according to EN 14387. identification colour brown
- Hand protection: Protective gloves according to EN 374.  
Glove material: Natural latex-Layer thickness: > 0.5 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:  
Do not breathe vapours. Avoid contact with skin and eyes. Change contaminated clothing.  
Wash hands before breaks and after work.  
Provide a conveniently located eye rinse station.

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

- Appearance: Form: liquid  
Colour: colourless, clear
- Odour: weak amine-like
- Odour threshold: No data available
- pH value: at 25 °C: 9.9 - 10.0
- 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



# SAFETY DATA SHEET

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

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|   |                      |
|---|----------------------|
| Flammability:                           | No data available    |
| Explosion limits:                       | No data available    |
| Vapour pressure:                        | No data available    |
| Vapour density:                         | No data available    |
| Density:                                | at 20 °C: 1.038 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

Additional information: No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

refer to 10.3

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reactions known.

### 10.4 Conditions to avoid

Protect against heat /sun rays.

### 10.5 Incompatible materials

strong acids and alkalis

### 10.6 Hazardous decomposition products

In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), carbon monoxide and carbon dioxide.

Thermal decomposition: No data available

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**SECTION 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): Based on available data, the classification criteria are not met.  
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 Dam. 1; H318 = Causes serious eye damage.  
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): STOT RE 2; H373 = May cause damage to organs through prolonged or repeated exposure.  
Aspiration hazard: Lack of data.

Other information: Information about Diethanolamine: LD50 Rat, oral 676 mg/kg.

**SECTION 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

**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.

##### Contaminated packaging

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:

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

### SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

##### National regulations - Great Britain

Hazchem-Code:

-

No data available

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### 15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

## SECTION 16: Other information

### Further information

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

H225 = Highly flammable liquid and vapour.

H301 = Toxic if swallowed.

H302 = Harmful if swallowed.

H311 = Toxic in contact with skin.

H315 = Causes skin irritation.

H318 = Causes serious eye damage.

H331 = Toxic if inhaled.

H370 = Causes damage to organs.

H373 = May cause damage to organs through prolonged or repeated exposure.

H412 = Harmful to aquatic life with long lasting effects.

Reason of change: Changes in section 2: Labelling (P-phrases: EU, ATP 8)

Date of first version: 6/3/2008

### Department issuing data sheet

Contact person: see section 1: Department 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.