

## 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.)

UFI: 3F30-E0CY-M00D-9SDM

### 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](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.

Precautionary statements:

P260	Do not breathe vapours.
P280	Wear protective gloves/protective clothing/eye 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.

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 of inorganic salts and organic compounds.

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 203-868-0 CAS 111-42-2	Diethanolamine Acute Tox. 4; H302. Skin Irrit. 2; H315. Eye Dam. 1; H318. STOT RE 2; H373. Aquatic Chronic 3; H412.	10 - 20 %
EC No. 200-659-6 CAS 67-56-1	Methanol Flam. Liq. 2; H225. Acute Tox. 3; H301. Acute Tox. 3; H311. Acute Tox. 3; H331. STOT SE 1; H370. Specific concentration limits (SCL): STOT SE 1; H370: $C \geq 10 \%$ / STOT SE 2; H371: $3 \% \leq C < 10 \%$	< 0,5 %

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.

In case of inhalation: Provide fresh air. If you feel unwell, seek medical advice.

Following skin contact: Take off contaminated clothing and wash it before reuse. 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. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

After swallowing: Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice. 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.

## 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:

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. If possible, eliminate leakage. Keep unprotected people away.  
Take off contaminated clothing and wash it before reuse.

## 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.

# 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. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. 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. Protect from light.  
Keep sterile.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.  
Do not store together with strong acids or alkalis.

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
111-42-2	Diethanolamine	Germany: TRGS 900 Kurzzeit	0,5 mg/m <sup>3</sup> ; 0,11 ppm (Aerosol and vapour, may be absorbed through the skin)
		Germany: TRGS 900 Langzeit	0,5 mg/m <sup>3</sup> ; 0,11 ppm (Aerosol and vapour, may be absorbed through the skin)
67-56-1	Methanol	Europe: IOELV: TWA	260 mg/m <sup>3</sup> ; 200 ppm (may be absorbed through the skin)
		Germany: TRGS 900 Kurzzeit	260 mg/m <sup>3</sup> ; 200 ppm (may be absorbed through the skin)
		Germany: TRGS 900 Langzeit	130 mg/m <sup>3</sup> ; 100 ppm (may be absorbed through the skin)

Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
67-56-1	Methanol	Germany: TRGS 903, urine	15 mg/L	Methanol	at long term exposure, end of exposure or end of shift

#### 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: Wear suitable protective clothing.

General protection and hygiene measures:  
Do not breathe vapours. Avoid contact with skin and eyes. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. 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:	colourless, clear
Odour:	weak amine-like
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:	at 25 °C: 10
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20 °C: 1,038 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

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 from frost, heat and sunlight.

### 10.5 Incompatible materials

Strong acids and alkalis

### 10.6 Hazardous decomposition products

	No decomposition when used properly.
Thermal decomposition:	No data available

### 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.

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.

#### 11.2 Information on other hazards

Endocrine disrupting properties: No data available

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

#### Symptoms

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

### SECTION 12: Ecological information

#### 12.1 Toxicity

Water Hazard Class: 1 = slightly 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, 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

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant: no

#### 14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

#### 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

Water Hazard Class: 1 = slightly hazardous to water

Information on working limitations:

Observe employment restrictions for young people.

Observe employment restrictions for expectant or nursing mothers.

Further regulations, limitations and legal requirements:

No data available

##### National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 3

### 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:

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: General revision

Date of first version: 6.3.2008

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

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 Chronic: Hazardous to the aquatic environment - chronic
- 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
- Eye Dam.: Eye damage
- Flam. Liq.: Flammable liquid
- 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
- LD50: Lethal dose 50%
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- 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 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
- 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.