



# SAFETY DATA SHEET

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

## Alkaline Phosphatase FS IFCC reagent R1

Material number 1 0411 R1

Revision date: 20.12.2022

Version: 4.1

Replaces version: 4.0

Language: en-DE

Date of print: 11.1.2023

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

#### 1.1 Product identifier

Trade name: Alkaline Phosphatase FS IFCC reagent R1

As part of the kits: 1 0411 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: 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)

This mixture is classified as not hazardous.

#### 2.2 Label elements

##### Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

##### Special labelling

EUH210 Safety data sheet available on request.

#### 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. 204-709-8 CAS 124-68-5	2-Amino-2-methylpropanol Skin Irrit. 2; H315. Eye Irrit. 2; H319. Aquatic Chronic 3; H412.	< 5 %

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

Additional information: Contains Sodium azide ( 0,95 g/L) as preservative.  
Contains in traces also zinc.

## SECTION 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: Change contaminated clothing. Remove residues with water. In case of skin irritation, consult a physician.

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 thoroughly with water. Induce vomiting.  
Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.

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

After eye contact: mild irritant

### 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 (NOx), carbon monoxide and carbon dioxide.

### 5.3 Advice for firefighters

Special protective equipment for firefighters:  
Wear self-contained breathing apparatus. Wear suitable 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

Avoid contact with skin, eyes, and clothing. Do not breathe vapours. Wear suitable protective clothing.  
In enclosed areas: 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. 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.  
Avoid contact with skin and eyes.  
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.  
Do not freeze. Keep sterile.

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
124-68-5	2-Amino-2-methylpropanol	Germany: TRGS 900 Kurzzeit	7,4 mg/m <sup>3</sup> ; 2 ppm (Aerosol and vapour, may be absorbed through the skin)
		Germany: TRGS 900 Langzeit	3,7 mg/m <sup>3</sup> ; 1 ppm (Aerosol and vapour, may be absorbed through the skin)

### 8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

### Personal protection equipment

#### Occupational exposure controls

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded.  
Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374.  
Glove material: Nitrile rubber  
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: Avoid contact with skin, eyes, and clothing. Change contaminated clothing.  
Do not breathe vapours. Wear appropriate protective equipment.  
Wash hands before breaks and after work.

### 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 30 °C: 10,4
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: approx. 1,011 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 against heat /sun rays.

### 10.5 Incompatible materials

Acids, 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:

- Acute toxicity (oral): Lack of data.
- 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: Based on available data, the classification criteria are not met.
- 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.

### 11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: Contains Sodium azide ( 0,95 g/L):  
After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

### Symptoms

After eye contact: mild irritant

## SECTION 12: Ecological information

### 12.1 Toxicity

Aquatic toxicity: Harmful to aquatic organisms.

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.



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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

##### Product

Waste key number: 06 03 13\* = Solid salts and solutions containing heavy metals.  
\* = 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.

##### Additional information

Discharge into the environment must be avoided.

### 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

Further regulations, limitations and legal requirements:  
No data available

##### National regulations - EC member states

Further regulations, limitations and legal requirements:  
No data available

### 15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

## SECTION 16: Other information

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

H315 = Causes skin irritation.

H319 = Causes serious eye irritation.

H412 = Harmful to aquatic life with long lasting effects.

EUH210 = Safety data sheet available on request.

Reason of change: General revision

Date of first version: 6.7.2007

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

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
- 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
- CNS: Central Nervous System
- DMEL: Derived minimal effect level
- DNEL: Derived no-effect level
- EC: European Community
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- 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
- 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
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- Skin Irrit.: Skin irritation
- 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.