

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
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)

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.

Alkaline Phosphatase FS DGKC Reagent R1

Material number 1 0401 R1

Page: 2 of 9

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.

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

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_x), 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. 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, 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. 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.

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	Ireland: 8 hours	1 mg/m ³ ; 0.2 ppm (inhalable fraction and vapour)
67-56-1	Methanol	Europe: IOELV: TWA	260 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		Great Britain: WEL-STEL	333 mg/m ³ ; 250 ppm (may be absorbed through the skin)
		Great Britain: WEL-TWA	266 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		Ireland: 8 hours	260 mg/m ³ ; 200 ppm (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: Wear suitable protective clothing.

Alkaline Phosphatase FS DGKC Reagent R1

Material number 1 0401 R1

Page: 5 of 9

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.

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:	weak amine-like
Odour threshold:	No data available
pH:	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
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 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 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.

Symptoms

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

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

12.2 Persistence and degradability

Further details: No data available



SAFETY DATA SHEET

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

Revision date: 31/3/2020
Version: 15
Language: en-GB,IE
Date of print: 12/3/2021

Alkaline Phosphatase FS DGKC Reagent R1

Material number 1 0401 R1

Page: 7 of 9

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.

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:

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



SAFETY DATA SHEET

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

Revision date: 31/3/2020
Version: 15
Language: en-GB,IE
Date of print: 12/3/2021

Alkaline Phosphatase FS DGKC Reagent R1

Material number 1 0401 R1

Page: 8 of 9

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

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

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.

Alkaline Phosphatase FS DGKC Reagent R1

Material number 1 0401 R1

Page: 9 of 9

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
OEL: Occupational Exposure Limit Value
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
EU: European Union
IATA: International Air Transport Association
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
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
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
TLV: Threshold Limit Value
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

Reason of change: Changes in section 2: Labelling
Changes in section 8: Occupational exposure limit values, biological limit values (Germany)
Changes in section 15: Regulatory information
General revision

Date of first version: 6/3/2008

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.

