

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

1.1 Product identifier

Trade name: CK-MB FS Reagent R2

As part of the kits: 1 1641 XX XX XXX
(The positions X code different packages.)

UFI: 5D10-80TF-800H-EKE2

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

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)

Repr. 1B; H360D May damage the unborn child.

2.2 Label elements

Labelling (CLP)



Signal word: **Danger**

Hazard statements: H360D May damage the unborn child.

Precautionary statements: P201 Obtain special instructions before use.
P280 Wear protective gloves/protective clothing/eye protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

Special labelling

Text for labelling: Contains Imidazole.
Restricted to professional users.

2.3 Other hazards

Product can cause eye irritation because of the pH-value.

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, contains phosphates

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 206-019-2 CAS 288-32-4	Imidazole Acute Tox. 4; H302. Skin Corr. 1C; H314. Repr. 1B; H360D.	< 0,5 %

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

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

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: Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Seek medical attention.

Following skin contact: Take off contaminated clothing and wash it before reuse. Remove residues with water. Seek medical treatment in case of troubles.

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. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Product can cause eye irritation because of the pH-value.

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 mixtureIn case of fire may be liberated: Nitrogen oxides (NO_x), phosphorus oxides, carbon monoxide and carbon dioxide.**5.3 Advice for firefighters**

Special protective equipment for firefighters:

Wear a self-contained breathing apparatus and chemical 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 and eyes. Wear appropriate protective equipment.
Avoid exposure. Do not breathe vapours. Take off contaminated clothing and wash it before reuse. 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. 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: Obtain special instructions before use. Avoid contact with skin and eyes. Wear appropriate protective equipment.
Keep all containers, equipment and working place clean. Avoid exposure. Do not breathe vapours. Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.

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.
Hints on joint storage: Do not store together with acids or alkalis. Keep away from food, drink and animal feedingstuffs.
Storage class: 6.1 D = Non-combustible substances of acute toxicity, category 3 / hazardous substances that are toxic or produce chronic effects

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

Personal protection equipment

Occupational exposure controls

Respiratory protection: If vapours form, use respiratory protection.
Use filter type A (= against vapours of organic substances) 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: Wear suitable protective clothing.

General protection and hygiene measures:

Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. Do not breathe vapours. Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. 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:	no characteristic odour
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: 9,0
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: 1,039 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. Protect from frost.

10.5 Incompatible materials

Acids, alkalis

10.6 Hazardous decomposition products

Thermal decomposition: No hazardous decomposition products when regulations for storage and handling are observed.
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): 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.

Product can cause eye irritation because of the pH-value.

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: Repr. 1B; H360D = May damage the unborn child.

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.

Information about Imidazole:
Reproduction toxicity: May damage the unborn child.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Contains phosphates: May contribute to the eutrophication of water supplies.

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



SAFETY DATA SHEET

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

CK-MB FS Reagent R2

Material number 1 1641 R2

Revision date: 20.12.2022

Version: 8.1

Replaces version: 8.0

Language: en-DE

Date of print: 11.1.2023

Page: 6 of 7

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: 6.1 D = Non-combustible substances of acute toxicity, category 3 / hazardous substances that are toxic or produce chronic effects

Water Hazard Class: 1 = slightly hazardous to water

Technical guidance air: 5.2.5

Information on working limitations:

Observe employment restrictions for young people.

Observe employment restrictions for expectant or nursing mothers.

Further regulations, limitations and legal requirements:

The product is controlled by the German Chemicals Prohibition Ordinance (ChemVerbotsV).

National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 3, 30

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:

H302 = Harmful if swallowed.

H314 = Causes severe skin burns and eye damage.

H360D = May damage the unborn child.

Reason of change: General revision

Date of first version: 17.7.2007

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

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

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

Repr.: Reproductive toxicity

RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail

Skin Corr.: Skin corrosion

TRGS: Technical Rules for Hazardous Substances

vPvB: Very persistent and very bioaccumulative

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.