

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

1.1 Product identifier

Trade Name: CK-MB Reagent R1

Article n°: 2120XXX

MS: 80115310126

1.2 Relevant identified uses of the substance or mixture and uses advised against

Reagent for *in-vitro* diagnostics in human samples

For professional use only.

1.3 Manufacturer

Kovalent do Brasil Ltda.

Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.

Tel: +(55 21) 2623-1367

e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number

Tel: +(55 21) 2623-1367 – Customer Service from 8am to 5pm

0800 015 1414

In case of emergency – 24 hours service

0800-722-6001 – RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture

Classification according to ABNT NBR 14725

H360D May damage the unborn child.

2.2 Label elements

Labelling (GHS)



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:

Contains Imidazole.

Restricted to professional users.

2.3 Other hazards

No risks worthy of mention.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution, contains phosphates.

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 206-019-2 CAS 288-32-4	Imidazole	< 0.5%	Acute Tox. 4; H302. Skin Corr. 1C; H314. Repr. 1B; H360D.

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

Additional information: Contains Sodium azide (0.95 g/L) as preservative.

4 First aid measures

4.1 Description of first aid measures

In case of inhalation:	Provide fresh air. Seek medical attention.
Following skin contact:	Take off contaminated clothing and wash it before reuse. Remove residues with 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 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

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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

In the event of a fire, the following may be produced when the water evaporates:
Nitrogen oxides (NOx), sulphur 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.

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.
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6.4 Reference to other sections

Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Advices on safe handling:

Avoid exposure - obtain special instructions before use. Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Keep all containers, equipment and working place clean. 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 feeding stuffs.

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.

8 Exposure controls/personal protection

8.1 Control parameters

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:

Obtain special instructions before use. Do not breathe vapours. Take off contaminated clothing and wash it before reuse. Avoid contact with skin, eyes, and clothing. 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".

9 Physical and chemical properties

Physical state at 20 °C and 101.3 kPa:

liquid

Colour:

colourless, clear

Odour:	weak like thiole
Odour threshold: pH:	No data available at 25 °C: 6.3
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: 1.009 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
Particle characteristics:	Not applicable
Viscosity:	No data available
Explosive properties:	No data available
Oxidizing characteristics:	No data available
Additional information:	No data available

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 reaction known.

10.4 Conditions to avoid

Protect against heat / sun rays. Protect from frost.

10.5 Incompatible materials

Acids and alkalis.

10.6 Hazardous decomposition products

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

Thermal decomposition: No data available

11 Toxicological information

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:	Lack of data.
Serious eye damage/irritation:	Lack of data.
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.

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 fertility or the unborn child.

12 Ecological information

12.1 Toxicity

Aquatic 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 Other adverse effects

General information: Do not allow to enter into groundwater, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Special waste. Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number

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ADR/RID, IMDG, IATA, ANTT: Not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA, ANTT: Not restricted

14.3 Transport hazard class(es)

ADR/RID: Not applicable
IMDG: Not applicable
IATA: Not applicable
ANTT: Not applicable

14.4 Risk Number

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14.5 Packing group

ADR/RID, IMDG, IATA, ANTT: Not applicable

14.6 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to regulations.
Marine pollutant: No

14.7 Special precautions for user

No dangerous good in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.
- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.
- This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The three X are for the volume

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.

Abbreviations and acronyms:

Acute Tox.: Acute toxicity
ABNT: Associação Brasileira de Normas Técnicas / National Standards Forum
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
ANTT: Agência Nacional de Transporte Terrestre / National Agency of Transportation 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

GHS: Globally Harmonized System
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
MS: Anvisa's Registry Code
NBR: Brazilian technical ordinance
OSHA: Occupational Safety and Health Administration
pH: Potential of Hydrogen
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
RDC: Resolution from the Directory Board
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RENACIAT: Rede Nacional de Centros de Informação e Assistência Toxicológica
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
TRGS: Technical Rules for Hazardous Substances
UN: United Nations

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

1.1 Product identifier

Trade Name: CK-MB Reagent R2
Article n°: 2120XXX
MS: 80115310126

1.2 Relevant identified uses of the substance or mixture and uses advised against

Reagent for *in-vitro* diagnostics in human samples
For professional use only.

1.3 Manufacturer

Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.
Tel: +(55 21) 2623-1367
e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number

Tel: +(55 21) 2623-1367 – Costumer Service from 8am to 5pm
0800 015 1414

In case of emergency – 24 hours service

0800-722-6001 – RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture

Classification according to ABNT NBR 14725
H360D May damage the unborn child.

2.2 Label elements

Labelling (GHS)



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.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization:

Aqueous solution, contains phosphates.

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Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 206-019-2 CAS 288-32-4	Imidazole	< 0.5%	Acute Tox. 4; H302. Skin Corr. 1C; H314. Repr. 1B; H360D.

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

Additional information: Contains Sodium azide (0.95 g/L) as preservative.

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.

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

In case of fire may be liberated: Nitrogen oxides (NOx), phosphorus oxides, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus and chemical protective clothing.

Additional information: Do not allow fire water to penetrate into surface or ground water.

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.

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 contaminated clothing off 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 feeding stuffs.

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.

8 Exposure controls/personal protection

8.1 Control parameters

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".

9 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
pH:	at 25 °C: 9.0
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: 1.039 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:	No data available
Explosive properties:	No data available
Particle characteristics:	Not applicable
Oxidizing characteristics:	No data available
Additional information:	No data available

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 and alkalis.

10.6 Hazardous decomposition products

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

Thermal decomposition: No data available

11 Toxicological information

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.
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

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

12.5 Other adverse effects

General information: Do not allow to enter groundwater, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Special waste. Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number

ADR/RID, IMDG, IATA, ANTT: Not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA, ANTT: Not restricted

14.3 Transport hazard class(es)

ADR/RID: Not applicable
IMDG: Not applicable
IATA: Not applicable
ANTT: Not applicable

14.4 Risk Number

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14.5 Packing group

ADR/RID, IMDG, IATA, ANTT: Not applicable

14.6 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to regulations
Marine pollutant: No

14.7 Special precautions for user

No dangerous good in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.
- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.
- This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The three X are for the volume

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.

Abbreviations and acronyms:

ABNT: Associação Brasileira de Normas Técnicas / National Standards Forum
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
ANTT: Agência Nacional de Transporte Terrestre / National Agency of Transportation 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
GHS: Globally Harmonized System
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
RENACIAT: Rede Nacional de Centros de Informação e Assistência Toxicológica
Repr.: Reproductive toxicity
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Skin Corr.: Skin corrosion
TRGS: Technical Rules for Hazardous Substances