

CREATINE KINASE MB_R2

| | | | |
|---------------|---------------------|---------|-----|
| Creation date | 02nd September 2015 | Version | 4.0 |
| Revision date | 21st August 2023 | | |

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

| | |
|---------------------|-----------------------|
| Substance / mixture | CREATINE KINASE MB_R2 |
| Number | mixture |
| UFI | BLT00018, XSYS0029 |
| Other mixture names | N6UU-UWN2-1J53-J11C |
| | CK MB 100, CK MB 110 |

1.2. Relevant identified uses of the substance or mixture and uses advised against**Mixture's intended use**

Reagent 2 is a part of kit CREATINE KINASE MB for quantitative in vitro determination of Creatine Kinase MB in human serum and plasma.

Main intended use

PC-MED-OTH Other medical devices

Secondary uses

PC-TEC-19 Reagents and laboratory chemicals

The use descriptors

PC 21 Laboratory chemicals

Mixture uses advised against

not available

1.3. Details of the supplier of the safety data sheet**Manufacturer**

| | |
|-----------------------------|-------------------------------|
| Name or trade name | Erba Lachema s.r.o. |
| Address | Karásek 2219/1d , Brno, 62100 |
| | Czech Republic |
| Identification number (CRN) | 26918846 |
| VAT Reg No | CZ26918846 |
| Phone | +420 517 077 111 |
| E-mail | msds@erba.com |
| Web address | www.erbalachema.com |

Competent person responsible for the safety data sheet

| | |
|--------|---------------------|
| Name | Erba Lachema s.r.o. |
| E-mail | msds@erba.com |

1.4. Emergency telephone number

European emergency number: 112 112

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification of the mixture in accordance with Regulation (EC) No 1272/2008**

The mixture is classified as dangerous.

Repr. 1B, H360D

Full text of all classifications and hazard statements is given in the section 16.

Most serious adverse effects on human health and the environment

May damage the unborn child.

2.2. Label elements**Hazard pictogram****Signal word**

Danger

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Hazardous substances

imidazole

Hazard statements

H360D May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

Mixture of substances and additives specified below.

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

| Identification numbers | Substance name | Content in % weight | Classification according to Regulation (EC) No 1272/2008 | Note |
|---|------------------|---------------------|---|------|
| Index: 613-319-00-0 CAS: 288-32-4 EC: 206-019-2 Registration number: 01-2119485825-24-x | imidazole | <1 | Acute Tox. 4, H302 Skin Corr. 1C, H314 Repr. 1B, H360D | 2 |
| Index: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5 | sodium hydroxide | <0,5 | Skin Corr. 1A, H314 Specific concentration limit: Skin Corr. 1B, H314: 2 % ≤ C < 5 % Skin Corr. 1A, H314: C ≥ 5 % Eye Irrit. 2, H319: 0.5 % ≤ C < 2 % Skin Irrit. 2, H315: 0.5 % ≤ C < 2 % | 1 |

Notes

- 1 A substance for which exposure limits are set.
- 2 The use of the substance is restricted by Annex XVII of REACH Regulation

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures**

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this Safety Data Sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

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If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Rinsing should continue at least for 10 minutes.

If swallowed

Never give anything by mouth to an unconscious person. Rinse out mouth. Provide medical treatment.

4.2. Most important symptoms and effects, both acute and delayed**If inhaled**

Not expected.

If on skin

Not expected.

If in eyes

Not expected.

If swallowed

Irritation, nausea.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Accommodate according to the location of the fire.

Unsuitable extinguishing media

Not known.

5.2. Special hazards arising from the substance or mixture

Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Wear a respiratory protective device and full protective clothing.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Pregnant women should strictly avoid inhalation and contact with the product.

Do not handle until all safety precautions have been read and understood.

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Obtain special instruction before use.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose. Protect the product from light. Avoid exposure to heat.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

For in vitro diagnostic devices.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

Czech Republic

Government Regulation 195/2021 Coll.

| Substance name (component) | Type | Value | Conversion for ppm | Note |
|-----------------------------------|-------|---------------------|--------------------|--|
| sodium hydroxide (CAS: 1310-73-2) | PEL | 1 mg/m ³ | | irritating to mucous membranes (eyes, respiratory system) and skin |
| | NPK-P | 2 mg/m ³ | | |

8.2. Exposure controls

Pregnant women should strictly avoid inhalation or skin contact.

Eye/face protection

Protective goggles or face shield (based on the nature of the work performed).

Skin protection

Hand protection: Protective gloves, impermeable and resistant to the product.

Protective work clothing.

Respiratory protection

Under good ventilation/ exhaust at the workplace, the use of these products should not require respiratory protection.

In case of brief exposure or low pollution use respiratory filter device.

In case of intensive or longer exposure use self-contained respiratory protective device.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|----------------------------------|
| Physical state | liquid |
| Colour | colourless |
| Odour | odourless |
| Melting point/freezing point | data not available |
| Boiling point or initial boiling point and boiling range | data not available |
| Flammability | data not available |
| Lower and upper explosion limit | data not available |
| Flash point | data not available |
| Auto-ignition temperature | data not available |
| Decomposition temperature | data not available |
| pH | 8.9 (undiluted at 20 °C) |
| Kinematic viscosity | data not available |
| Solubility in water | data not available |
| Partition coefficient n-octanol/water (log value) | data not available |
| Vapour pressure | data not available |
| Density and/or relative density | |
| Density | 1.051 g/cm ³ at 20 °C |
| Relative vapour density | data not available |
| Particle characteristics | data not available |

9.2. Other information

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not available

SECTION 10: Stability and reactivity**10.1. Reactivity**

Stable at the recommended storage temperature and if protected from light.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoidThe product is stable and no degradation occurs under normal conditions.
Avoid exposure to heat.**10.5. Incompatible materials**

Strong oxidizing agents, strong acids.

10.6. Hazardous decomposition products

Dangerous outcomes such as carbon monoxide and carbon dioxide, heavy smoke and nitrogen oxides, phosphorus oxides and sodium oxides are formed at high temperature and in fire.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

No toxicological data is available for the mixture.

Acute toxicity

Based on available data the classification criteria are not met.

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|-----------------------|-----------|--------------|---------------|---------|-----|----------------------|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex | Value determination |
| Oral | ATE | 160000 mg/kg | | | | Calculation of value |

| imidazole | | | | | | |
|-------------------|------------------|-----------|---------------|-------------------------|-----|---------------------|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex | Value determination |
| Oral | LD ₅₀ | 880 mg/kg | | Mouse | | |
| | LD ₅₀ | 970 mg/kg | | Rat (Rattus norvegicus) | | |

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.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

May damage the unborn child.

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Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Based on available data the classification criteria are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information**12.1. Toxicity**

not available

Acute toxicity

| imidazole | | | | |
|------------------|------------|---------------|---------|-------------|
| Parameter | Value | Exposure time | Species | Environment |
| EC ₅₀ | 231 mg/l | 30 minutes | | |
| EC ₅₀ | 341.5 mg/l | 48 hours | | |

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

Waste type code

16 05 06 laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals *

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Packaging waste type code

15 01 10 packaging containing residues of or contaminated by hazardous substances *

(*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

SECTION 14: Transport information**14.1. UN number or ID number**

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

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Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

imidazole

| Restriction | Conditions of restriction |
|-------------|---|
| 30 | <p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: <ul style="list-style-type: none"> — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>"Restricted to professional users".</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: <ul style="list-style-type: none"> — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date. (f) devices covered by Regulation (EU) 2017/745. |

15.2. Chemical safety assessment

Assessment was not carried out.

SECTION 16: Other information

A list of standard risk phrases used in the safety data sheet

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H360D May damage the unborn child.

Guidelines for safe handling used in the safety data sheet

P201 Obtain special instructions before use.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR European agreement concerning the international carriage of dangerous goods by road
BCF Bioconcentration Factor
CAS Chemical Abstracts Service
CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC Identification code for each substance listed in EINECS

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| EC ₅₀ | Concentration of a substance when it is affected 50% of the population |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| EmS | Emergency plan |
| EU | European Union |
| EuPCS | European Product Categorisation System |
| IATA | International Air Transport Association |
| IBC | International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods |
| IMO | International Maritime Organization |
| INCI | International Nomenclature of Cosmetic Ingredients |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| LD ₅₀ | Lethal dose of a substance in which it can be expected death of 50% of the population |
| log K _{ow} | Octanol-water partition coefficient |
| NPK | Maximum admissible concentration |
| OEL | Occupational Exposure Limits |
| PBT | Persistent, Bioaccumulative and Toxic |
| PEL | Permissible Exposure Limit |
| ppm | Parts per million |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Agreement on the transport of dangerous goods by rail |
| UN | Four-figure identification number of the substance or article taken from the UN Model Regulations |
| UVCB | Substances of unknown or variable composition, complex reaction products or biological materials |
| VOC | Volatile organic compounds |
| vPvB | Very Persistent and very Bioaccumulative |
| Acute Tox. | Acute toxicity |
| Repr. | Reproductive toxicity |
| Skin Corr. | Skin corrosion |

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

For in vitro diagnostic use only.

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 4.0 replaces the SDS version from 07 April 2021. Changes were made in sections 1, 2, 11, 12, 13, 15 and 16.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.