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

1.1 Product identifier

<table>
<thead>
<tr>
<th>CREATININE ENZYMATIC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pack Name</strong></td>
</tr>
<tr>
<td><strong>Cat. No.</strong></td>
</tr>
<tr>
<td><strong>Reagent 1</strong></td>
</tr>
</tbody>
</table>

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

Diagnostic reagent for quantitative in vitro determination of Creatinine in human serum, plasma and urine.

1.3 Details of the supplier of the safety data sheet

Name of manufacturer: Erba Lachema s.r.o.
Place of business: Brno, Karásek 1d, postcode 621 00, CZ
ID no: 26918846
Phone: +420 517 077 111
E-mail: msds@erbalachema.com

1.4 Emergency telephone number

Erba Lachema s.r.o.
Phone: +420 517 077 556 (service only during business hours)
Toxicological Information Centre (TIS), Na Bojišti 1, 128 01 Prague 2
Phone: +420 224 919 293 or +420 224 915 402 (service available 24 hours a day)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Reagent 1
Classification according to Regulation (EC) No 1272/2008
Mixture is not classified as hazardous.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives.

2.3 Other hazards

Mixture or components are not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

The product is a mixture.

3.2 Mixtures

Reagent 1 contains no hazardous substances above limits that need to be mentioned in this section according to applicable EU-legislation.
SECTION 4: First aid measures

4.1 Description of first aid measures
No special measures required.

Exposure by inhalation
Discontinue the exposure.

Exposure by contact with skin
After contact with skin, wash with soap and water.

Exposure by contact with eyes
Rinse an open eye (hold eyelids with fingers) with plenty of water for about 15 minutes.

Exposure by ingestion
Rinse mouth with water, drink 1/2 l of lukewarm water.

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
No data available.

SECTION 5: Firefighting measures

The mixture is not flammable. The measure should be adapted to burning substances in the surrounding area.

5.1 Extinguishing media
For the mixture no limitations of extinguishing media are given.

5.2 Special hazards arising from the substance or mixture
None known.

5.3 Advice for firefighters
No special advice.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment, see Section 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

6.2 Environmental precautions
Due to amount of chemical substances in a mixture, an impact on the environment is not expected.

6.3 Methods and material for containment and cleaning up
Absorb spilled agent with a suitable inert material (sand, earth, vapex) and store contaminated material in containers for collection of hazardous waste. For waste disposal, see Section 13.

6.4 Reference to other sections
See section 7, 8 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling
Observe the principles of work in laboratory. Observe the normal operating procedures for handling chemical substances and mixtures. Do not eat, drink or smoke. Use personal protective equipment, see Section 8.

7.2 Conditions for safe storage, including any incompatibilities
Store in dry and covered stores in tightly closed containers at a temperature between +2 °C and +8 °C.

7.3 Specific end use(s)
The kit is designed for in vitro diagnostic devices.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Control parameters are not defined according to Government Decree No 361/2007 Coll.
Exposure limit values in the workplace are not defined according to Directive No 2006/15/EC.
Limit values for indicators of biological exposure tests are not defined according to Decree No 432/2003 Coll.

8.2 Exposure controls
Appropriate engineering controls
Not required.

Personal protective equipment
a. Eye/face protection
Not required.
b. Hand protection
Not required.
c. Skin protection
Not required.
d. Respiratory protection
Not required.
e. Thermal hazards
None known.

Environmental exposure controls
To eliminate the emergency conditions, have pre-prepared a decontamination mixture and appropriate collection vessels for reaction residues. Dispose of reaction residues and decontaminated mixtures as hazardous waste water in accordance with relevant legal regulations.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Reagent 1
a. Appearance .......................................................... Liquid
b. Odour ........................................................................ Odourless
c. Odour threshold .......................................................... Information not available
d. pH (at 20 °C) ............................................................. 7.5
e. Melting point/freezing point................................. Information not available
f. Initial boiling point and boiling range (°C) .................................. Information not available

g. Flash point (°C) .................................. Information not available

h. Evaporation rate .................................. Information not available

i. Flammability (solid, gas) .................................. Information not available

j. Upper/lower flammability or explosive limits .................................. Information not available

k. Vapour pressure (hPa) .................................. Information not available

l. Vapour density .................................. Information not available

m. Relative density (g cm⁻³) .................................. 1.006

n. Water solubility .................................. Information not available

o. Partition coefficient: n-octanol/water .................................. Information not available

p. Autoignition temperature (°C) .................................. Information not available

q. Decomposition temperature (°C) .................................. Information not available

r. Viscosity .................................. Information not available

s. Explosive properties .................................. Information not available

t. Oxidizing properties .................................. Information not available

9.2 Other information

None.

SECTION 10: Stability and reactivity

Under normal conditions of use and storage the mixture is stable.

10.1 Reactivity

No data available.

10.2 Chemical stability

The mixture is stable at normal temperature and pressure.

10.3 Possibility of hazardous reactions

Not known.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity

Based on available data, the classification criteria are not met.

b) Irritability

Based on available data, the classification criteria are not met.

c) Corrosion

Based on available data, the classification criteria are not met.
Name of the mixture: CREATININE ENZYMATIC

d) **Sensitization**
Based on available data, the classification criteria are not met.

e) **Repeated dose toxicity**
Based on available data, the classification criteria are not met.

f) **Carcinogenicity**
Based on available data, the classification criteria are not met.

g) **Mutagenicity**
Based on available data, the classification criteria are not met.

h) **Reproductive toxicity**
Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

12.1 **Toxicity**
The mixture is not classified as toxic to the environment.

12.2 **Persistence and degradability**
No data available.

12.3 **Bioaccumulative potential**
No data available.

12.4 **Mobility in soil**
No data available.

12.5 **Results of PBT and vPvB assessment**
The product does not have the properties of PBT and vPvB. Assessment based on the ingredients that do not have properties of PBT and vPvB.

12.6 **Other adverse effects**
There is no information about any special danger for environment.

### SECTION 13: Disposal considerations

13.1 **Waste treatment methods**
Dispose of in compliance with applicable regulations for hazardous waste management. Do not drain into the wastewater. The mixture should be discarded as a laboratory waste. Incinerate residues of the mixture in a hazardous waste incinerator. Contaminated packaging must be treated as hazardous waste.

### SECTION 14: Transport information

Not governed by regulations for transport of dangerous goods (ADR).

14.1 **UN number**
Not specified.

14.2 **UN proper shipping name**
ADR/RID: –
IMDG: –
ICAO/IATA: –
Safety Data Sheet

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Name of the mixture: CREATININE ENZYMATIC

14.3 Transport hazard class(es)
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.4 Packing group
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.5 Environmental hazards
The mixture is not hazardous to the environment during transport.

14.6 Special precautions for user
No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not transported.

SECTION 15: Regulatory information
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety data sheet complies with the requirements of Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP).

15.2 Chemical safety assessment
Assessment was not carried out.

SECTION 16: Other information
Recommended restrictions on use
This compound is designed for professional use. It should not be used for purposes other than those described in Section 1.2.

Information about data sources used to compile the Safety Data Sheet
Material Safety Data Sheets of raw material suppliers, ECHA (European Chemicals Agency), corporate documentation for products.

Declaration
The safety data sheet contains basic data corresponding to the present state of our knowledge and experience, in accordance with applicable regulations. The foregoing information was gathered with the utmost care, but that does not mean that it is complete and should be used as the only correct information. Erba Lachema s.r.o. is not responsible for any damages caused by improper use and handling of the mixture.
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

<table>
<thead>
<tr>
<th>CREATININE ENZYMATIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pack Name</td>
</tr>
<tr>
<td>Cat. No.</td>
</tr>
<tr>
<td>Reagent 2</td>
</tr>
</tbody>
</table>

1.1 Relevant identified uses of the substance or mixture and uses advised against
Diagnostic reagent for quantitative *in vitro* determination of Creatinine in human serum, plasma and urine.

1.2 Details of the supplier of the safety data sheet

Name of manufacturer: Erba Lachema s.r.o.
Place of business: Brno, Karásek 1d, postcode 621 00, CZ
ID no: 26918846
Phone: +420 517 077 111
E-mail: msds@erbalachema.com

1.3 Emergency telephone number

Erba Lachema s.r.o.
Phone: +420 517 077 556 (*service only during business hours*)
Toxicological Information Centre (TIS), Na Bojišti 1, 128 01 Prague 2
Phone: +420 224 919 293 or +420 224 915 402 (*service available 24 hours a day*)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Reagent 2
Classification according to Regulation (EC) No 1272/2008
Mixture is not classified as hazardous.

2.2 Label elements
The product does not need to be labelled in accordance with EC directives.

2.3 Other hazards
Mixture or components are not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances
The product is a mixture.
3.2 Mixtures
Reagent 2 contains following hazardous substances:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Content (% of weight)</th>
<th>CAS number</th>
<th>EC number</th>
<th>Index number</th>
<th>Reg. number</th>
<th>Specific Concentration limits, M-factors</th>
<th>Classification according to 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-morpholino-propane-sulphonic acid</td>
<td>&lt;3.0</td>
<td>1132-61-2</td>
<td>214-478-5</td>
<td>–</td>
<td>–</td>
<td>Skin Irrit. 2</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2</td>
<td>STOT SE 3</td>
<td></td>
<td>H319 H335</td>
</tr>
</tbody>
</table>

For a full text of H-statements see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures
No special measures required.

Exposure by inhalation
Discontinue the exposure.

Exposure by contact with skin
After contact with skin, wash with soap and water.

Exposure by contact with eyes
Rinse an open eye (hold eyelids with fingers) with plenty of water for about 15 minutes.

Exposure by ingestion
Rinse mouth with water, drink 1/2 l of lukewarm water.

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
No data available.

SECTION 5: Firefighting measures
The mixture is not flammable. The measure should be adapted to burning substances in the surrounding area.

5.1 Extinguishing media
For the mixture no limitations of extinguishing media are given.

5.2 Special hazards arising from the substance or mixture
None known.

5.3 Advice for firefighters
No special advice.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment, see Section 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.
6.2 Environmental precautions
Due to amount of chemical substances in a mixture, an impact on the environment is not expected.

6.3 Methods and material for containment and cleaning up
Absorb spilled agent with a suitable inert material (sand, earth, vapex) and store contaminated material in containers for collection of hazardous waste. For waste disposal, see Section 13.

6.4 Reference to other sections
See section 7, 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Observe the principles of work in laboratory. Observe the normal operating procedures for handling chemical substances and mixtures. Do not eat, drink or smoke. Use personal protective equipment, see Section 8.

7.2 Conditions for safe storage, including any incompatibilities
Store in dry and covered stores in tightly closed containers at a temperature between +2 °C and +8 °C.

7.3 Specific end use(s)
The kit is designed for in vitro diagnostic devices.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Control parameters are not defined according to Government Decree No 361/2007 Coll.
Exposure limit values in the workplace are not defined according to Directive No 2006/15/EC.
Limit values for indicators of biological exposure tests are not defined according to Decree No 432/2003 Coll.

8.2 Exposure controls
Appropriate engineering controls
Not required.

Personal protective equipment
a. Eye/face protection
Not required.
b. Hand protection
Not required.
c. Skin protection
Not required.
d. Respiratory protection
Not required.
e. Thermal hazards
None known.

Environmental exposure controls
To eliminate the emergency conditions, have pre-prepared a decontamination mixture and appropriate collection vessels for reaction residues. Dispose of reaction residues and decontaminated mixtures as hazardous waste water in accordance with relevant legal regulations.
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Reagent 2

a. Appearance ................................................................. Light brown liquid
b. Odour ................................................................. Odourless
c. Odour threshold .......................................................... Information not available
d. pH (at 20 °C) .......................................................... 7.5
e. Melting point/freezing point ............................................... Information not available
f. Initial boiling point and boiling range (°C) ................................ Information not available
g. Flash point (°C) .......................................................... Information not available
h. Evaporation rate .......................................................... Information not available
i. Flammability (solid, gas) ................................................ Information not available
j. Upper/lower flammability or explosive limits ................................ Information not available
k. Vapour pressure (hPa) .................................................. Information not available
l. Vapour density .......................................................... Information not available
m. Relative density (g cm\(^{-3}\)) ........................................... 1.006
n. Water solubility .......................................................... Soluble
o. Partition coefficient: n-octanol/water .................................... Information not available
p. Autoignition temperature (°C) .......................................... Information not available
q. Decomposition temperature (°C) ....................................... Information not available
r. Viscosity ................................................................. Information not available
s. Explosive properties ..................................................... Information not available
t. Oxidizing properties ..................................................... Information not available

9.2 Other information

None.

SECTION 10: Stability and reactivity

Under normal conditions of use and storage the mixture is stable.

10.1 Reactivity

No data available.

10.2 Chemical stability

The mixture is stable at normal temperature and pressure.

10.3 Possibility of hazardous reactions

Not known.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.
SECTION 11: Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity
Based on available data, the classification criteria are not met.

b) Irritability
Based on available data, the classification criteria are not met.

c) Corrosion
Based on available data, the classification criteria are not met.

d) Sensitization
Based on available data, the classification criteria are not met.

e) Repeated dose toxicity
Based on available data, the classification criteria are not met.

f) Carcinogenicity
Based on available data, the classification criteria are not met.

g) Mutagenicity
Based on available data, the classification criteria are not met.

h) Reproductive toxicity
Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity
The mixture is not classified as toxic to the environment.

12.2 Persistence and degradability
No data available.

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil
No data available.

12.5 Results of PBT and vPvB assessment
The product does not have the properties of PBT and vPvB. Assessment based on the ingredients that do not have properties of PBT and vPvB.

12.6 Other adverse effects
There is no information about any special danger for environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Dispose of in compliance with applicable regulations for hazardous waste management. Do not drain into the wastewater. The mixture should be discarded as a laboratory waste. Incinerate residues of the mixture in a hazardous waste incinerator. Contaminated packaging must be treated as hazardous waste.
SECTION 14: Transport information

Not governed by regulations for transport of dangerous goods (ADR).

14.1 UN number
Not specified.

14.2 UN proper shipping name
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.3 Transport hazard class(es)
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.4 Packing group
ADR/RID: –
IMDG: –
ICAO/IATA: –

14.5 Environmental hazards
The mixture is not hazardous to the environment during transport.

14.6 Special precautions for user
No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not transported.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety data sheet complies with the requirements of Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP).

15.2 Chemical safety assessment
Assessment was not carried out.

SECTION 16: Other information

List of H-statements
H-statements: H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Recommended restrictions on use
This compound is designed for professional use. It should not be used for purposes other than those described in Section 1.2.
Information about data sources used to compile the Safety Data Sheet

Material Safety Data Sheets of raw material suppliers, ECHA (European Chemicals Agency), corporate documentation for products.

Declaration

The safety data sheet contains basic data corresponding to the present state of our knowledge and experience, in accordance with applicable regulations. The foregoing information was gathered with the utmost care, but that does not mean that it is complete and should be used as the only correct information. Erba Lachema s.r.o. is not responsible for any damages caused by improper use and handling of the mixture.