

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 1 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

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

#### 1.1 Product identifier

CREATININE		
<b>Product Name</b>	CREA 1000	CREA 200
<b>Catalog Number</b>	BLT00019	BLT00020
<b>Reagent 1</b>	2 x 250 ml	2 x 50 ml
<b>Reagent 2</b>	2 x 250 ml	2 x 50 ml
<b>Calibrator</b>	2 x 5 ml	1 x 5 ml

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

The sets are designed for Health Service laboratories for determination of creatinine concentration in serum and plasma. The mixture is intended for professional use.

#### 1.3 Details of the supplier of the safety data sheet

Name or trade name of manufacturer: Erba Lachema s.r.o.  
Place of business: Brno, Karásek 1d, postcode 621 00  
ID no.: 26918846  
Phone: +420 517 077 579  
Fax: +420 517 077 077  
Qualified person: Ing. Pavel Filka  
E-mail: [filka@erbalachema.com](mailto:filka@erbalachema.com)  
Phone: +420 517 077 556

#### 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*)

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013	Date of review:	Page 2 of 10 pages	Version: 1
--------------------------	-----------------	--------------------	------------

Name of the mixture: **CREATININE**

## 2 Hazards Identification

### 2.1 Classification of the mixture

Reagent 1

The reagent 1 of the kit **Creatinine** is classified as dangerous according to EU Directives 1999/45/EC as amended

**Xi, Irritant; R 36/38** Irritating to eyes and skin

### 2.2 Label elements

**Xi**



Symbols:

**Irritant**

*Risk phrases (R):*

R 36/38 Irritating to eyes and skin

*Safety phrases (S):*

S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 28 After contact with skin, wash immediately with plenty of water.

S 37/39 Wear suitable gloves and eye/face protection.

S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

## 3 Composition/information on ingredients

### 3.1 Composition

The reagent 1 contains the following hazardous substances:

Substance name	Content (% of weight)	CAS number	EC number	Classification according to (EC) No. 67/548 EEC
				Classification according to (EC) No. 1272/2008
<b>Sodium hydroxide*</b>	1.6%	1310-73-2	215-185-5	C, R35; S 26-37/39-45 Skin Corr. 1A; H314; P280, P310, P305+P351+P338

The reagent 2 contains the following hazardous substances:

Substance name	Content (% of weight)	CAS number	EC number	Classification according to (EC) No. 67/548 EEC
				Classification according to (EC) No. 1272/2008
<b>Picric acid</b>	0.4	88-89-1	201-865-9	T, E; R 2-4-23/24/25; S 36/37-35-45 Expl. 1.1; Acute Tox. 3; H201 H301, H311, H331; P261, P280, P301+310, P311, P370+P380, P501.
<b>Sodium hydroxide*</b>	< 0.04%	1310-73-2	215-185-5	C, R35; S 26-37/39-45 Skin Corr. 1A; H314; P280, P310, P305+P351+P338

The calibrator contains the following hazardous substances:

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 3 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

Substance name	Content (% of weight)	CAS number	EC number	Classification according to (EC) No. 67/548 EEC
				Classification according to (EC) No. 1272/2008
<b>Benzoic acid</b>	0.16%	65-85-0	200-618-2	Xn, R 22-36/37/38-42/43; S 2-22-26-36/37-46 Resp. Sens. 1, Acute Tox. 4, STOT SE 3, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H334, H302, H335, H 319, H317, H315; P280, P285, P261, P405, P501 P305+P351+P338

\*) Substance with exposure limits (exposure limits are listed in Chapter 8.1)

For a full text of R-phrases, S-phrases, H-phrases and P-phrases see Section 16.

## 4 First aid measures

### 4.1 Description of first aid measures

When working with the mixture, take care of personal hygiene and prevent contamination of work clothing and skin. If you have any doubts or when symptoms persist, seek medical attention.

#### Exposure by inhalation

Discontinue the exposure, remove casualty to fresh air, keep at rest and seek medical advice.

#### Exposure by contact with skin

Take off all contaminated clothing. After contact with skin, wash immediately 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, transfer casualty to a specialist.

#### Exposure by ingestion

Rinse mouth with water, drink 1/2 l of lukewarm water, seek medical attention immediately, do not induce vomiting.

### 4.2 Most important symptoms and effects, both acute and delayed

None

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

No data available

## 5 Fire-fighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

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

#### Unsuitable extinguishing media

None known.

### 5.2 Special hazards arising from the substance or mixture

None

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 4 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

### 5.3 Advice for firefighters

Protective clothing, breathing apparatus.

## 6 Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment, see item 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

### 6.2 Environmental precautions

Do not discharge into the drains, surface waters, groundwater.

### 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 item 13.

Sweep solid reagent and store in containers for collection of hazardous waste. For waste disposal see item 13.

## 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 item 8.

### 7.2 Conditions for safe storage, including any incompatibilities

Store in tightly closed containers at a temperature between +2°C and +25°C.

### 7.3 Specific end use

The kit is designed for in vitro diagnostic devices.

## 8 Exposure controls/personal protection

### 8.1 Exposure limit values

**Control parameters** of the mixture components according to Government Decree No. 361/2007 Coll.

CAS	Substance name	PEL	NPK-P	Note	Conversion factor for ppm
		mg/m <sup>3</sup>	mg/m <sup>3</sup>		
1310-73-2	Sodium hydroxide	1	2	-	-

*PEL - Permissible exposure limits; NPK-P - the maximum permissible concentration; D - a significant penetration of the substance through the skin or a strong irritating effect on the skin during exposure; S - the substance has a sensitizing effect; P - serious late effects of the substance cannot be excluded; \* - the physico-chemical properties (e.g. explosiveness) are taken into account for NPK-P.*

**Exposure limit values in the workplace** according to Directive No. 2006/15/EC

No data Available

**Limit values for indicators of biological exposure tests in urine** for the product according to Decree No. 432/2003 Coll.

No data Available

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013	Date of review:	Page 5 of 10 pages	Version: 1
--------------------------	-----------------	--------------------	------------

Name of the mixture: **CREATININE**

### 8.2 Exposure controls

#### 8.2.1 Appropriate engineering controls

None

#### 8.2.2 Personal protective equipment

- A) Respiratory protection: Not required with adequate ventilation, otherwise breathing apparatus.
- B) Hand protection: Protective gloves - rubber, resistant to caustic substances.
- C) Eye protection: Safety goggles.
- D) Skin protection: Protective clothing:

#### 8.2.3 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.

## 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Reagent 1

- a. Appearance..... Clear colorless liquide
- b. Odour..... no data available
- c. Odour Threshold ..... no data available
- d. pH (při 20°C) ..... >12,5
- e. Melting point / freezing point..... no data available
- f. Initial boiling point and boiling range (°C) ..... no data available
- g. Flash point (°C) ..... no data available
- h. Evaporation rate ..... no data available
- i. Flammability (solid, gas)..... no data available
- j. Upper/lower flammability or explosive limits ..... no data available
- k. Vapour pressure (hPa)..... no data available
- l. Vapour density ..... no data available
- m. Relative density (kg.m-3)..... no data available
- n. Water solubility ..... no data available
- o. Partition coefficient: n- octanol/water..... no data available
- p. Autoignition temperature (°C) ..... no data available
- q. Decomposition temperature (°C) ..... no data available
- r. Viscosity..... no data available
- s. Explosive properties..... no data available
- t. Oxidizing properties..... no data available

#### Reagent 2

- a. Appearance..... Clear yellow liquide
- b. Odour..... no data available
- c. Odour Threshold ..... <4,5
- d. pH (při 20°C) ..... no data available
- e. Melting point / freezing point..... no data available
- f. Initial boiling point and boiling range (°C) ..... no data available
- g. Flash point (°C) ..... no data available
- h. Evaporation rate ..... no data available
- i. Flammability (solid, gas)..... no data available

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 6 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

- j. Upper/lower flammability or explosive limits ..... no data available
- k. Vapour pressure (hPa)..... no data available
- l. Vapour density ..... no data available
- m. Relative density (kg.m-3)..... no data available
- n. Water solubility ..... no data available
- o. Partition coefficient: n- octanol/water..... no data available
- p. Autoignition temperature (°C) ..... no data available
- q. Decomposition temperature (°C) ..... no data available
- r. Viscosity..... no data available
- s. Explosive properties..... no data available
- t. Oxidizing properties..... no data available

### Standard (Calibrator)

- a. Appearance..... Clear colorless liquide
- b. Odour..... no data available
- c. Odour Threshold ..... no data available
- d. pH (při 20°C) ..... no data available
- e. Melting point / freezing point..... no data available
- f. Initial boiling point and boiling range (°C) ..... no data available
- g. Flash point (°C) ..... no data available
- h. Evaporation rate ..... no data available
- i. Flammability (solid, gas)..... no data available
- j. Upper/lower flammability or explosive limits ..... no data available
- k. Vapour pressure (hPa)..... no data available
- l. Vapour density ..... no data available
- m. Relative density (kg.m-3)..... no data available
- n. Water solubility ..... no data available
- o. Partition coefficient: n- octanol/water..... no data available
- p. Autoignition temperature (°C) ..... no data available
- q. Decomposition temperature (°C) ..... no data available
- r. Viscosity..... no data available
- s. Explosive properties..... no data available
- t. Oxidizing properties..... no data available

## 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

No data available

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

Avoid exposure to heat of solar radiation

### 10.5 Incompatible material

Heavy Metals, strong oxidizing agents and strong acids

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 7 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

### 10.6 Hazardous decomposition products

Nitrogen oxide and carbon

## 11 Toxicological information

### 11.1 Acute toxicity

Human oral LD<sub>50</sub> (g.kg<sup>-1</sup>)..... not applicable

Rat oral LD<sub>50</sub> (g.kg<sup>-1</sup>)..... not applicable

Rat inhalation LD<sub>50</sub> (g.kg<sup>-1</sup>)..... not applicable

Rat inhalation TLS (g.kg<sup>-1</sup>)..... not applicable

### 11.2 Skin corrosion/irritation

Not applicable.

### 11.3 Serious eye damage/eye irritation

Not applicable.

### 11.4 Respiratory or skin sensitization

Not applicable.

### 11.5 Germ cell mutagenicity

Not applicable.

### 11.6 Carcinogenicity

Not applicable.

### 11.7 Reproductive toxicity

Not applicable.

### 11.8 Specific target organ toxicity - single exposure

Not applicable.

### 11.9 Specific target organ toxicity - repeated exposure

Not applicable.

### 11.10 Aspiration hazard

Not applicable.

## 12 Ecological information

### 12.1 Ecotoxicity

Waste water

LC<sub>50</sub> 96 hrs, fish (mg.kg<sup>-1</sup>)..... not applicable

EC<sub>50</sub> 48 hrs, daphnia (mg.kg<sup>-1</sup>)..... not applicable

IC<sub>50</sub> 72 hrs algae (mg.kg<sup>-1</sup>)..... not applicable

CHSK..... not applicable

BSK<sub>5</sub>..... not applicable

### 12.2 Persistence and degradability

Not applicable.

### 12.3 Bioaccumulative potential

Not applicable.

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 8 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

### 12.4 Mobility in soil

Not applicable.

### 12.5 Results of PBT and vPvB assessment

Not applicable.

### 12.6 Other adverse effects

Not applicable.

## 13 Disposal considerations

### 13.1 Waste treatment methods

Dispose of in compliance with applicable regulations for hazardous waste management. Incinerate residues of the mixture in a hazardous waste incinerator.

Contaminated packaging must be treated as hazardous waste. Dispose of by incinerating in a hazardous waste incinerator.

## 14 Transport information

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

### 14.1 UN number

ADR/RID:

IMDG:

IATA:

### 14.2 UN proper shipping name

ADR/RID:

IMDG:

IATA:

### 14.3 Transport hazard class(es)ADR/RID:

IMDG:

IATA:

### 14.4 Packaging group

ADR/RID:

IMDG:

IATA:

### 14.5 Environmental hazards

ADR/RID:

IMDG:

IATA:

### 14.6 Special precautions for user

No data available

## 15 Regulatory Information

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

no data available



## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 9 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

### 15.2 Chemical Safety

no data available

### 16 Further information

#### List of R-phrases:

- R 1 Explosive when dry.
- R 4 Forms very sensitive explosive metallic compounds.
- R 11 Highly flammable.
- R 22 Harmful if swallowed.
- R 23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
- R 35 Causes severe burns.
- R 36/37/38 Irritating to eyes, respiratory system and skin.
- R 42/43 May cause sensitization by inhalation and skin contact.

#### List of H-phrases:

- H201 Explosive; mass explosion hazard.
- H301 Toxic if swallowed.
- H311 Toxic in contact with skin.
- H331 Toxic if inhaled.
- H314 Causes severe skin burns and eye damage.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H317 May cause an allergic skin reaction.
- H335 May cause respiratory irritation.

#### List of P-phrases:

- P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
- P280 Wear protective gloves/ protective clothing.
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
- P311 Call a POISON CENTER or doctor/ physician.
- P370+P380 In case of fire: Evacuate area.
- P501 Dispose of contents/ container to an approved waste disposal plant.
- 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 Immediately call a POISON CENTER or doctor/ physician.
- P285 In case of inadequate ventilation wear respiratory protection.
- P405 Store locked up.
- P501 Container dispose in accordance with local / regional / national / international regulations.

#### List of S-phrases:

- S 2 Keep out of the reach of children.
- S 22 Do not breathe dust.
- S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S 35 This material and its container must be disposed of in a safe way.
- S 36/37 Wear suitable protective clothing and gloves.

## Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 1.2. 2013

Date of review:

Page 10 of 10 pages

Version: 1

Name of the mixture: **CREATININE**

S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 46 If swallowed, seek medical advice immediately and show this container or label.

S 37/39 Wear suitable gloves and eye/face protection.

### Training instructions

Workers who come into contact with hazardous materials shall be acquainted by the organization, to a necessary extent, with the effects of these substances, with the methods how to treat them, with protective measures, the principles of first aid, necessary sanitation procedures and procedures for liquidation of failures and accidents. Under Article 35 of the European Parliament and Council Regulation (EC) No. 1907/2006, the employer must enable employees or their representatives access to information from the safety data sheet of the substance or mixture the worker uses or the effects of which can be exposed to during his/her work.

### Recommended restrictions on use

The mixture is intended for professional use. It should not be used for purposes other than those listed under 1.2.

### Further information

Information given is based on our best knowledge and is intended to describe the product for the purposes of safety of transporting and handling only. It should not be therefore construed as guaranteeing any specific property of the product. It is the responsibility of the user to observe all current regulations and consider recommendations on the use of application of product.

### 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.*