

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

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

- 1.1. Product identifier** SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2
- Substance / mixture mixture
 Number 140345
 Other mixture names
 SOUPRAVA na BARVENÍ MOČOVÉHO SEDIMENTU; STERNHEIMERUV BARVICI ROZTOK, Supravital colouring by STERNHEIMER
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
 The set is intended for in vitro microscopy of urine sediment.
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**
Distributor
 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.erba.com
- Manufacturer**
 Name or trade name Oy Reagen Ltd.
 Address Takojantie 18, FIN-70900, TOIVALA
 Finland
 Phone +358 10 5045 200
 E-mail info@reagen.com
 Web address www.reagen.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.
- Aquatic Chronic 3, H412
Most serious adverse effects on human health and the environment
 Harmful to aquatic life with long lasting effects.
- 2.2. Label elements**
Hazard statements
 H412 Harmful to aquatic life with long lasting effects.
Precautionary statements
 P273 Avoid release to the environment.

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

P501 Dispose of contents/container to in accordance with local regulations.

Supplemental information

EUH208 Contains Basic Red 1. May produce an allergic reaction.

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. Does not contain any PMT or vPvM components.

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: 613-348-00-9 CAS: 989-38-8 EC: 213-584-9 | Basic Red 1 | <0.75 | Acute Tox. 3, H301 Skin Sens. 1, H317 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Specific concentration limit: ATE Oral = 280 mg/kg bw | |

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 inhaled

Terminate the exposure immediately; move the affected person to fresh air. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

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.

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. Seek (professional) medical attention, especially if pain or redness of eyes persists.

If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

Not expected.

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

Symptomatic treatment.

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

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

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

As a result of combustion or thermal decomposition reactive subproducts are created that can become highly toxic and, consequently, can present a serious health risk.

5.3. Advice for firefighters

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...). Collect contaminated firefighting water separately. 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**

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

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Retain contaminated washing water and dispose it. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities. Suitable material for taking up: absorbing material, organic, sand.

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. Keep containers hermetically sealed. Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used. Product is non-flammable under normal conditions of storage, manipulation and use. Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

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. Avoid sources of heat, radiation, static electricity and contact with food.

Storage temperature

min 10 °C, max 25 °C

7.3. Specific end use(s)

The reagent of the kit is designed for in vitro diagnostic use.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

The mixture contains no substances for which occupational exposure limits are set. The mixture contains substances for which occupational exposure limits are set.

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest. As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding "CE marking". For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer.

Eye/face protection

Protective goggles (tightly sealed).

Skin protection

Hand protection: Protective gloves resistant to the product. Contaminated skin should be washed thoroughly. Replace the gloves at any sign of deterioration. Work clothing. Anti-slip work shoes.

Respiratory protection

It is not needed.

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 | red |
| Odour | data not available |
| Melting point/freezing point | data not available |
| Boiling point or initial boiling point and boiling range | 100 °C |
| Flammability | The product is non-flammable. |
| Lower and upper explosion limit | data not available |
| Flash point | >60 °C |
| Auto-ignition temperature | data not available |
| Decomposition temperature | data not available |
| pH | 3.9 (undiluted) |
| Kinematic viscosity | data not available |
| Solubility in water | data not available |
| Partition coefficient n-octanol/water (log value) | data not available |
| Vapour pressure | 2350 at 20 °C |
| Density and/or relative density | |
| Density | 1030 g/cm ³ at 20 °C |
| Relative density | 1.03 |
| Relative vapour density | data not available |
| Particle characteristics | data not available |

9.2. Other information

| | |
|----------------------|---|
| Appearance | red liquid |
| Oxidising properties | The product has no oxidizing properties. |
| Explosive properties | The product does not have explosive properties. |

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

not available

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Not known. Unknown.

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Depending on the decomposition conditions mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

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

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

| SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2 | | | | | | |
|---|-----------|-------------|---------------|---------|-----|----------------------|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex | Value determination |
| Oral | ATE | 37838 mg/kg | | | | Calculation of value |

| Basic Red 1 | | | | | | |
|-------------------|------------------|--------------|---------------|---------|-----|---------------------|
| Route of exposure | Parameter | Value | Exposure time | Species | Sex | Value determination |
| Oral | LD ₅₀ | 100 mg/kg | | Rat | | |
| Dermal | LD ₅₀ | 2000 mg/kg | | | | |
| Oral | ATE | 280 mg/kg bw | | | | |

Skin corrosion/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Serious eye damage/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Respiratory or skin sensitisation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

11.2. Information on other hazards**Endocrine disrupting properties**

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption for humans.

Other information

not available

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

Harmful to aquatic life with long lasting effects.

Acute toxicity**Basic Red 1**

| Parameter | Value | Exposure time | Species | Environment |
|------------------|------------|---------------|---|-------------|
| EC ₅₀ | 0.16 mg/l | 48 hours | Invertebrates (Daphnia magna) | |
| EC ₅₀ | 0.023 mg/l | 72 hours | Algae (Pseudokirchneriella subcapitata) | |

12.2. Persistence and degradability

No data are available for either the mixture or the components.

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

12.5. Results of PBT and vPvB assessment

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any PBT or vPvB components. 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

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption in the environment.

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. 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.

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

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

(*) - 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).

15.2. Chemical safety assessment

not available

SECTION 16: Other information**A list of standard risk phrases used in the safety data sheet**

| | |
|--------|---|
| EUH208 | Contains Basic Red 1. May produce an allergic reaction. |
| H301 | Toxic if swallowed. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H412 | Harmful to aquatic life with long lasting effects. |

Guidelines for safe handling used in the safety data sheet

| | |
|------|--|
| P273 | Avoid release to the environment. |
| P501 | Dispose of contents/container to in accordance with local regulations. |

Other important information about human health protection

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

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

| | |
|------------------|---|
| Acute Tox. | Acute toxicity |
| ADR | Agreement concerning the international carriage of dangerous goods by road |
| Aquatic Acute | Hazardous to the aquatic environment |
| Aquatic Chronic | Hazardous to the aquatic environment (chronic) |
| 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 |
| 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 |
| Eye Dam. | Serious eye damage |
| 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 Kow | Octanol-water partition coefficient |
| OEL | Occupational Exposure Limits |
| PBT | Persistent, bioaccumulative and toxic |
| PMT | Persistent, mobile and toxic |
| ppm | Parts per million |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Agreement on the transport of dangerous goods by rail |
| Skin Sens. | Skin sensitization |
| UN number | 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 |
| vPvM | Very persistent and very mobile |

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

not available

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 3.0 replaces the SDS version from Tuesday, 25 June 2024. Changes were made in sections 2, 11, 12, 13 and 16.

SET for COLOURING of URINE SEDIMENT (REASTAIN URINE)_R2

| | | | |
|---------------|----------------|---------|-----|
| Creation date | 22nd July 2019 | Version | 3.0 |
| Revision date | 11th June 2025 | | |

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.
