

08.03.2023

## Kit Components

Product code	Description
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<b>R3921</b>	<b>Premi®Test Urin</b>
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Components:

R3921P01	Premi® Test Urin Sample Buffer
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# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 08.03.2023

Version number 3.0

Revision: 08.03.2023

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

#### 1.1 Product identifier

**Trade name:** Premi® Test Urin Sample Buffer

**Article number:** R3921P01

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

No further relevant information available.

**Application of the substance / the preparation:** In vitro

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

**Manufacturer/Supplier:**

R-Biopharm AG

An der neuen Bergstraße 17

D-64297 Darmstadt

**Further information obtainable from:** e-mail: [info@r-biopharm.de](mailto:info@r-biopharm.de)

#### 1.4 Emergency telephone number:

CHEMTREC (worldwide): +1 703-741-5970 / 1-800-424-9300

CHEMTREC (United Kingdom): 44-870-8200418 and 44-2038073798 (toll free)

For additional worldwide local emergency numbers refer to section 16.

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



Eye Irrit. 2 H319 Causes serious eye irritation.

#### 2.2 Label elements

**Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the GB CLP regulation.

**Hazard pictograms** GHS07

**Signal word** Warning

**Hazard statements**

H319 Causes serious eye irritation.

**Precautionary statements**

P264 Wash thoroughly after handling.

P280 Wear eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

#### 2.3 Other hazards

**Results of PBT and vPvB assessment**

**PBT:** Not applicable.


**vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

#### 3.2 Chemical characterisation: Mixtures

**Description:** Mixture: consisting of the following components.

**Dangerous components:**

10035-04-8	calcium chloride, dihydrate	 Eye Irrit. 2, H319	25 – 50%
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**Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

**After inhalation:** Supply fresh air; consult doctor in case of complaints.

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**After swallowing:** If symptoms persist consult doctor.

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

No further relevant information available.

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

No further relevant information available.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

**Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

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

No further relevant information available.

#### 5.3 Advice for firefighters

**Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

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

Wear protective clothing.

#### 6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

#### 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

#### 6.4 Reference to other sections

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Open and handle receptacle with care.

No special precautions are necessary if used correctly.

**Information about fire - and explosion protection:** No special measures required.

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

**Storage:**

**Requirements to be met by storerooms and receptacles:** No special requirements.

**Information about storage in one common storage facility:** Not required.

**Further information about storage conditions:** Keep container tightly sealed.

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**7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Additional information about design of technical facilities:** No further data; see item 7.**Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**Additional information:** The lists valid during the making were used as basis.

#### 8.2 Exposure controls

**Personal protective equipment:****General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

**Respiratory protection:** Not required.**Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

**Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

**Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**For the permanent contact gloves made of the following materials are suitable:**

Nitrile rubber, NBR

Recommended thickness of the material:  $\geq 0.11$  mm

Value for the permeation: Level  $\leq 480$

**As protection from splashes gloves made of the following materials are suitable:**

Nitrile rubber, NBR

Recommended thickness of the material:  $\geq 0.11$  mm

Value for the permeation: Level  $\leq 480$

**Eye protection:**

Tightly sealed goggles

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

##### General Information

##### Appearance:

Form:	Fluid
Colour:	Colourless
Odour:	Undistinguishable.
Odour threshold:	Not determined.

pH-value: Not determined.

##### Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

Flash point: Not applicable.

Flammability (solid, gas): Not applicable.

Decomposition temperature: Not determined.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

##### Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

Vapour pressure at 20 °C: 23 hPa

Density: Not determined.

Relative density: Not determined.

Vapour density: Not determined.

Evaporation rate: Not determined.

Solubility in / Miscibility with water:

Fully miscible.

Partition coefficient: n-octanol/water: Not determined.

##### Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

##### Solvent content:

Water: 50.0 %

Solids content: 0.0 %

#### 9.2 Other information

No further relevant information available.

### SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

#### 10.2 Chemical stability

##### Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid No further relevant information available.

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**10.5 Incompatible materials:** No further relevant information available.**10.6 Hazardous decomposition products:** No dangerous decomposition products known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

**Acute toxicity** Based on available data, the classification criteria are not met.**Primary irritant effect:****Skin corrosion/irritation** Based on available data, the classification criteria are not met.**Serious eye damage/irritation**

Causes serious eye irritation.

**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.**Additional toxicological information:****CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)****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** Based on available data, the classification criteria are not met.**STOT-single exposure** Based on available data, the classification criteria are not met.**STOT-repeated exposure** Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1 Toxicity

**Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**12.3 Bioaccumulative potential** No further relevant information available.**12.4 Mobility in soil** No further relevant information available.**Additional ecological information:****General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**12.5 Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.**12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

**Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

**Uncleaned packaging:****Recommendation:** Disposal must be made according to official regulations.

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**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

#### SECTION 14: Transport information

<b>14.1 UN-Number</b> ADR, ADN, IMDG, IATA	Void
<b>14.2 UN proper shipping name</b> ADR, ADN, IMDG, IATA	Void
<b>14.3 Transport hazard class(es)</b> ADR, ADN, IMDG, IATA Class	Void
<b>14.4 Packing group</b> ADR, IMDG, IATA	Void
<b>14.5 Environmental hazards:</b> <b>Marine pollutant:</b>	No
<b>14.6 Special precautions for user</b>	Not applicable.
<b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
<b>Transport/Additional information:</b>	Not dangerous according to the above specifications.
<b>UN "Model Regulation":</b>	Void

#### SECTION 15: Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
**Directive 2012/18/EU**
**Named dangerous substances - ANNEX I** None of the ingredients is listed.

**National regulations:**
**Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

**15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

#### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**Relevant phrases**

H319 Causes serious eye irritation.

**Department issuing SDS:** QS 0049-6151-8102-0

**Contact:** QS 0049-6151-8102-0

**Worldwide local emergency numbers**

Argentina Spanish Local (City) Buenos Aires Americas 54-1159839431

Australia English Local (City) Sydney Oceania 61-290372994

Austria German Local (City) Vienna Europe 43-13649237

Belgium French Local (City) Brussels Europe 32-28083237

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Brazil Portuguese Local (City) Rio De Janeiro Americas 55-2139581449  
 Brazil Portuguese Local (City) Sao Paulo Americas 55-1143491359  
 Brazil - Toll Free Portuguese Toll free Mobile-Enabled Americas 0800 892 0479  
 Bulgaria Bulgarian Local (City) Plovdiv Europe 359-32570104  
 Cayman Islands English Local (National) Americas 345-749-8392  
 Chile Spanish Local (City) Santiago Americas 56 2 2581 4934  
 China Mandarin Local (National) Asia 4001-204937  
 Colombia Spanish Toll Free Americas 01800-710-2151  
 Costa Rica Spanish Local (National) Americas 506-40003869  
 Croatia Croatian Local (City) Zagreb Europe 385-17776920  
 Czech Republic Czech Local (City) Prague Europe 420-228880039  
 Denmark Danish Local (National) Europe 45-69918573  
 Dominican Republic Spanish Local (City) Santo Domingo Americas (829) 956-7588  
 El Salvador Spanish Local (City) San Salvador Americas 503 2136 7633  
 Estonia Estonian Local (National) Europe 372-6681294  
 Finland Finnish Local (City) Helsinki Europe 358-942419014  
 France French National Europe 33-975181407  
 Germany German Local (City) Frankfurt Europe 49-69643508409 0800-181-7059  
 Greece Greek Local (City) Athens Europe 30-2111768478  
 Grenada English Local (City) St George Americas 1 (473) 230-0165  
 Guinea French Americas 224 660 71 03 00  
 Hong Kong Toll Free Asia 800-968-793  
 Hungary Hungarian Local (City) Budapest Europe 36-18088425  
 Iceland Icelandic Local (City) Reykjavik Europe 354 539 0655  
 India Hindi, Bengali, English Asia 000-800-100-7141  
 Indonesia Indonesian Toll Free Asia 001-803-017-9114  
 Ireland English Local (City) Dublin Europe 353-19014670  
 Israel Hebrew Local (City) Tel Aviv Asia 972-37630639  
 Italy Italian Local (City) Milan Europe 39-0245557031 800-789-767  
 Japan Japanese Local (City) Tokyo Asia 81-345209637  
 Latvia Latvian Lettish Local (City) Riga Europe 371-66165504  
 Lithuania Lithuanian Local (City) Vilnius Europe 370-52140238  
 Luxembourg French and German Europe 352-20202416  
 Macedonia Macedonian Local (City) Skopje Europe 389 2 551 7456  
 Malaysia Malay Local (City) Kuala Lumpur Asia 60-39212579 41-800-815-308  
 Mexico Spanish Americas 01-800-681-9531  
 Netherlands Dutch Europe 31-858880596  
 New Zealand English Local (City) Auckland Oceania 64-98010034  
 Nigeria Hausa Local (City) Lagos Europe 234 1 227 8883  
 Panama Spanish Local (National) Americas 507-8322475  
 Peru Spanish Local (City) Lima Americas 51-17071295  
 Philippines Tagalog Local (City) Manila Asia 1-800-1-116-1020  
 Poland Polish Local (City) Warsaw Europe 48-223988029  
 Portugal Portuguese Local (National) Europe 351-308801773  
 Romania Romanian Local (National) Europe 40-37-6300026  
 Russia Russian Toll Free Mobile-Enabled Asia 8-800-100-6346  
 Saudi Arabia Arabic and English CHEMTREC DID Only Asia 966-8111095861  
 Singapore English and Mandarin Asia 65-31581349 or 800-101-2201  
 Slovakia Slovak Local (City) Bratislava Europe 421-233057972  
 Slovenia Slovenian Local (City) Ljubljana Europe 38-618888016  
 South Africa English Toll Free Africa 0-800-983-611  
 South Korea Korean Toll Free Asia 003-0813-2549 and 080-822-1374  
 Spain Spanish Local (City) Barcelona Europe 34-931768545 and 900-868538  
 Sweden Swedish Local (City) Stockholm Europe 46-852503403  
 Switzerland German and French and Italian Zurich Europe 41-435082011  
 Taiwan Mandarin Local (City) Taipei Asia 886-2-7741-4207 and 00801-14-8954  
 Thailand Thai Toll Free Asia 01-800-13-203-9987

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Trinidad and Tobago English Local (National) Americas 1-868-224-5716

Turkey Turkish Local (City) Istanbul Europe 90-212-7055340

Ukraine Ukrainian Europe 380-947101374

United Kingdom English Local (City) London Europe 44-870-8200418 and 44-2038073798

**Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

**\* Data compared to the previous version altered.**

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