

# Safety data sheet

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

Printing date 27.06.2022

Version number 6.0

Revision: 27.06.2022

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

#### 1.1 Product identifier

**Trade name:** Premi@Test 25 Ampoule**Article number:** R3925

#### 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**

The product is not classified, according to the CLP regulation.

#### 2.2 Label elements

**Labelling according to Regulation (EC) No 1272/2008** Void**Hazard pictograms** Void**Signal word** Void**Hazard statements** Void

#### 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 of substances with nonhazardous additions.**Dangerous components:** Void**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

**General information:** No special measures required.**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.**After swallowing:** If symptoms persist consult doctor.

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

No further relevant information available.

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**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:** No special measures required.**6.3 Methods and material for containment and cleaning up:** Pick up mechanically.**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** No special measures required.**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:** None.**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:**

The usual precautionary measures are to be adhered to when handling chemicals.

**Respiratory protection:** Not required.

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**Protection of hands:**

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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:**

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

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

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

**Eye protection:** Safety glasses

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

**General Information****Appearance:**

<b>Form:</b>	Solid
<b>Colour:</b>	Violet
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

**pH-value:** Not applicable.

**Change in condition**

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.

**Flash point:** Not applicable.

**Flammability (solid, gas):** Not determined.

**Decomposition temperature:** Not determined.

**Auto-ignition temperature:** Product is not selfigniting.

**Explosive properties:** Product does not present an explosion hazard.

**Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

**Vapour pressure:** Not applicable.

**Density:** Not determined.

**Relative density** Not determined.

**Vapour density** Not applicable.

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<b>Evaporation rate</b>	Not applicable.
<b>Solubility in / Miscibility with water at 60 °C:</b>	20 g/l
<b>Partition coefficient: n-octanol/water:</b>	Not determined.
<b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
<b>Solvent content:</b>	
<b>Solids content:</b>	100.0 %
<b>9.2 Other information</b>	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.

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

**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.

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**Additional ecological information:****General notes:** Not hazardous for water.**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** Disposal must be made according to official regulations.**Uncleaned packaging:****Recommendation:** Disposal must be made according to official regulations.**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

**14.1 UN-Number****ADR, ADN, IMDG, IATA** Void**14.2 UN proper shipping name****ADR, ADN, IMDG, IATA** Void**14.3 Transport hazard class(es)****ADR, ADN, IMDG, IATA**  
**Class** Void**14.4 Packing group****ADR, IMDG, IATA** Void**14.5 Environmental hazards:****Marine pollutant:** No**14.6 Special precautions for user**

Not applicable.

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

**Transport/Additional information:**

Not dangerous according to the above specifications.

**UN "Model Regulation":**

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:** Generally not hazardous for water.

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**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.

**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  
 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

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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  
 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:**

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

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

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