

04.04.2022

### Kit Components

Product code	Description
<b>GZ3016</b>	<b>RIDA®TUBE Calprotectin</b>
Components:	
GZ3016T05	RIDA®TUBE Calprotectin

# Safety data sheet

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

Printing date 04.04.2022

Version number 3.0

Revision: 04.04.2022

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

#### 1.1 Product identifier

**Trade name:** RIDA®TUBE Calprotectin

**Article number:** GZ3016T05

#### 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

#### 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



Acute Tox. 4 H332 Harmful if inhaled.

#### 2.2 Label elements

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

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

**Hazard pictograms** GHS07

**Signal word** Warning

##### Hazard-determining components of labelling:

guanidinium chloride

##### Hazard statements

H332 Harmful if inhaled.

##### Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

#### 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.

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**Dangerous components:**

CAS: 50-01-1	guanidinium chloride	5-10%
EINECS: 200-002-3	⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319	

**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:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

**After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

**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.

**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:** Mouth respiratory protective device.**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).

Ensure adequate ventilation.

**6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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### SECTION 7: Handling and storage

**7.1 Precautions for safe handling** Prevent formation of aerosols.

**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.

**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:** Wash hands before breaks and at the end of work.

**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  $\leq 480$

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Eye protection:



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

#### Appearance:

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

pH-value at 20 °C: 7.2

#### Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C

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 at 20 °C:	1.06044 g/cm <sup>3</sup>
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: 85.8 %

Solids content: 14.2 %

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**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.**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**

Harmful if inhaled.

**LD/LC50 values relevant for classification:****50-01-1 guanidinium chloride**

Oral LD50 556.5 mg/kg (rat)

Dermal LD50 &gt;2,000 mg/kg (rabbit)

**6132-04-3 Tri-Natriumcitrat-Dihydrat**

Oral LD50 &gt;8,000 mg/kg (rat)

**77-86-1 trometamol**

Oral LD50 &gt;5,000 mg/kg (rat)

Dermal LD50 &gt;5,000 mg/kg (rat)

**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:****50-01-1 guanidinium chloride**

EC50/48h 70.2 mg/l (aquatic invertebrates)

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ErC50/72h 33.5 mg/l (Algae)

**77-86-1 trometamol**

EC50/48h &gt;980 mg/l (aquatic invertebrates)

ErC50/48h 473 mg/l (Algae)

**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.**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:**

Not applicable.

**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.

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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:** 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

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

**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

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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  
 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

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