

# Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 17.07.2017

Version number 1

Revision: 17.07.2017

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

### 1.1 Product identifier

**Trade name:** RIDASCREEN® Leishmania IgG Postive control

**Article number:** K7321C01

### 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:** FE e-mail: info@r-biopharm.de

**1.4 Emergency telephone number:** FE 0049-6151-8102-0

## 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:**

contains human serum <0,1%

Inactivated human serum < 0,1%

**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:**

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** 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****Additional information about design of technical facilities:** No further data; see item 7.**8.1 Control parameters****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 trough 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 trough 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

**Eye protection:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties****General Information****Appearance:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Colourless
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

<b>pH-value at 20 °C:</b>	7.4
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**Change in condition**

<b>Melting point/freezing point:</b>	0 °C
<b>Initial boiling point and boiling range:</b>	>100 °C

<b>Flash point:</b>	Not applicable.
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<b>Flammability (solid, gas):</b>	Not applicable.
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**Ignition temperature:**

<b>Decomposition temperature:</b>	Not determined.
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<b>Auto-ignition temperature:</b>	Product is not selfigniting.
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<b>Explosive properties:</b>	Product does not present an explosion hazard.
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**Explosion limits:**

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

<b>Vapour pressure at 20 °C:</b>	23 hPa
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<b>Density:</b>	Not determined.
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not determined.

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<b>Evaporation rate</b>	Not determined.
<b>Solubility in / Miscibility with water:</b>	Fully miscible.
<b>Partition coefficient: n-octanol/water:</b>	Not determined.
<b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
<b>Solvent content:</b>	
<b>Organic solvents:</b>	0.0 %
<b>Water:</b>	98.6 %
<b>Solids content:</b>	1.3 %
<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.

**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:**

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**

Autoclaving or dispose of as hazardous waste.  
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.

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**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.

**Department issuing SDS:** QS 0049-6151-8102-0**Contact:** QS 0049-6151-8102-0**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 européen sur le transport 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

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