

# Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 17.07.2018

Version number 1

Revision: 15.03.2017

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

### 1.1 Product identifier

**Trade name:** RIDASCREEN® *Helicobacter* Conjugate 2

**Article number:** C2302K02

### 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:** 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.

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

No further relevant information available.

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## 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

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.

#### Protection of hands:

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

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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:** 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>	Orange
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

**pH-value at 20 °C:** 7

**Change in condition**

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

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

**Vapour pressure at 20 °C:** 23 hPa

<b>Density:</b>	Not determined.
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not determined.
<b>Evaporation rate</b>	Not determined.

**Solubility in / Miscibility with water:**

Fully miscible.

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<b>Partition coefficient: n-octanol/water:</b>	Not determined.
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**Viscosity:****Dynamic:**

Not determined.

**Kinematic:**

Not determined.

**Solvent content:****Organic solvents:**

0.0 %

**Water:**

100.0 %

**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.**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.**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.

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**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:**

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.

**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.

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## 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:**

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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