

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.12.2015

Version number 4

Revision: 15.12.2015

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

1.1 Product identifier

Trade name: **RIDASCREEN® Haemo-Haptoglobin Complex Calibrator**

Article number: G09031C04

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

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

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 Void

Signal word Void

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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.

(Contd. on page 2)

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Trade name: RIDASCREEN® Haemo-Haptoglobin Complex Calibrator

(Contd. of page 1)

Dangerous components:

CAS: 57-50-1 EINECS: 200-334-9	sucrose, pure substance with a Community workplace exposure limit	50-100%
CAS: 26628-22-8 EINECS: 247-852-1	sodium azide T+ R28 N R50/53 R32 Acute Tox. 2, H300 Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0,1-1%

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.

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:

 CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

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 Open and handle receptacle with care.

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

(Contd. on page 3)

Safety data sheet

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(Contd. of page 2)

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:

57-50-1 sucrose, pure

WEL	Short-term value: 20 mg/m ³
	Long-term value: 10 mg/m ³

26628-22-8 sodium azide

WEL	Short-term value: 0.3 mg/m ³
	Long-term value: 0.1 mg/m ³ (as NaN ₃), Sk

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: ≥ 0.11 mmValue for the permeation: Level ≤ 480
As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.11 mmValue for the permeation: Level ≤ 480

(Contd. on page 4)

GB

Safety data sheet

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Version number 4

Revision: 15.12.2015

Trade name: RIDASCREEN® Haemo-Haptoglobin Complex Calibrator

Eye protection:

(Contd. of page 3)



Tightly sealed goggles

SECTION 9: Physical and chemical properties

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

Form:	Solid
Colour:	White
Odour:	Characteristic
Odour threshold:	Not determined.

pH-value:	Not applicable.
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Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

Flash point:	Not applicable.
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Flammability (solid, gaseous):	Not determined.
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Ignition temperature:

Decomposition temperature:	Not determined.
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Self-igniting:	Product is not selfigniting.
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Danger of explosion:	Product does not present an explosion hazard.
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Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

Vapour pressure:	Not applicable.
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Density:	Not determined.
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Relative density	Not determined.
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Vapour density	Not applicable.
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Evaporation rate	Not applicable.
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Solubility in / Miscibility with water:

Soluble.

Partition coefficient (n-octanol/water):	Not determined.
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Viscosity:

Dynamic:	Not applicable.
Kinematic:	Not applicable.

Solvent content:

Organic solvents:	0.0 %
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Solids content:	100.0 %
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9.2 Other information	No further relevant information available.
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GB

(Contd. on page 5)

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(Contd. of page 4)

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.

LD/LC50 values relevant for classification:

57-50-1 sucrose, pure

Oral	LD50	29700 mg/kg (rat)
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26628-22-8 sodium azide

Oral	LD50	27 mg/kg (rat)
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Dermal	LD50	20 mg/kg (rabbit)
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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.

Ecotoxicological effects:

Remark: Harmful to fish

Additional ecological information:

General notes:

Generally not hazardous for water

Harmful to aquatic organisms

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

GB

(Contd. on page 6)

Safety data sheet

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(Contd. of page 5)

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:

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.

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.

(Contd. on page 7)

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(Contd. of page 6)

Relevant phrases

H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R28 Very toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Department issuing MSDS: 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity, Hazard Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

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

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