

Product code	Description
PG2305	RIDA®GENE Helicobacter pylori

Components:

PGZ2305PC	RIDA®GENE Helicobacter pylori Positive Control
PGZ2305RM	RIDA®GENE Helicobacter pylori Reaction Mix
PGZ2305EM	RIDA®GENE Helicobacter pylori Taq-Polymerase
PGZ2305IC	RIDA®GENE Helicobacter pylori Internal Control DNA
PGZ2305NC	RIDA®GENE Helicobacter pylori No Template Control

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

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

1.1 Product identifier

Trade name: RIDA®GENE Helicobacter pylori Positive Control

Article number: PGZ2305PC

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

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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Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Positive Control

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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

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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Trade name: RIDA®GENE Helicobacter pylori Positive Control

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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: Goggles recommended during refilling

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: 8

Change in condition

Melting point/freezing point:	0 °C
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:	0.997 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

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Trade name: RIDA®GENE Helicobacter pylori Positive Control

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Solubility in / Miscibility with water:

Fully miscible.

Partition coefficient: n-octanol/water:

Not determined.

Viscosity:
Dynamic:

Not determined.

Kinematic:

Not determined.

Solvent content:
Water:

95.0 %

Solids content:

5.0 %

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.

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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Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Positive Control

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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** 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:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

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Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Positive Control

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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
 Portugal Portuguese Local (National) Europe 351-308801773
 Romania Romanian Local (National) Europe 40-37-6300026

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Trade name: RIDA®GENE Helicobacter pylori Positive Control

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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.**

GB

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** RIDA®GENE *Helicobacter pylori* Reaction Mix**Article number:** PGZ2305RM**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**

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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Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Reaction Mix

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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

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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Safety data sheet

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Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Reaction Mix

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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: Goggles recommended during refilling

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:	8
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Change in condition

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

Flash point:	Not applicable.
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Flammability (solid, gas):	Not applicable.
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Decomposition temperature:	Not determined.
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Auto-ignition temperature:	Product is not selfigniting.
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Explosive properties:	Product does not present an explosion hazard.
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Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

Vapour pressure at 20 °C:	23 hPa
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Density at 20 °C:	0.997 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

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Trade name: RIDA®GENE Helicobacter pylori Reaction Mix

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Solubility in / Miscibility with water:

Fully miscible.

Partition coefficient: n-octanol/water:

Not determined.

Viscosity:
Dynamic:

Not determined.

Kinematic:

Not determined.

Solvent content:
Water:

95.0 %

Solids content:

5.0 %

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.

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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Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Reaction Mix

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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** 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:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

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Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Reaction Mix

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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
 Portugal Portuguese Local (National) Europe 351-308801773
 Romania Romanian Local (National) Europe 40-37-6300026

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Printing date 15.02.2022

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Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Reaction Mix

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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.**

GB

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

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

1.1 Product identifier

Trade name: RIDA®GENE *Helicobacter pylori* Taq-Polymerase

Article number: PGZ2305EM

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

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:

CAS: 56-81-5

glycerol

substance with a Community workplace exposure limit

5-10%

EINECS: 200-289-5

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.

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Trade name: RIDA®GENE Helicobacter pylori Taq-Polymerase

(Contd. of page 1)

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: 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

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:

56-81-5 glycerol

WEL Long-term value: 10 mg/m³

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.

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Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Taq-Polymerase

(Contd. of page 2)

Respiratory protection: Not required.

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: Goggles recommended during refilling

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:	8
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Change in condition

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

Flash point:	160 °C
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Flammability (solid, gas):	Not applicable.
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Ignition temperature:	400 °C
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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
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Density at 20 °C:	1.0157 g/cm ³
Relative density	Not determined.

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Safety data sheet

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Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Taq-Polymerase

(Contd. of page 3)

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:	
Organic solvents:	7.1 %
Water:	91.9 %
Solids content:	1.0 %
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.

LD/LC50 values relevant for classification:

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
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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.

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.

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Safety data sheet

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Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Taq-Polymerase

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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.

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

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Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Taq-Polymerase

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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

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

GB

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

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

1.1 Product identifier

Trade name: RIDA®GENE *Helicobacter pylori* Internal Control DNA

Article number: PGZ2305IC

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

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.

(Contd. on page 2)

Safety data sheet

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Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Internal Control DNA

(Contd. of page 1)

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****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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Safety data sheet

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Printing date 15.02.2022

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Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Internal Control DNA

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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: Goggles recommended during refilling

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: 8

Change in condition

Melting point/freezing point:	0 °C
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: 0.997 g/cm³

Relative density Not determined.

Vapour density Not determined.

Evaporation rate Not determined.

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Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Internal Control DNA

(Contd. of page 3)

Solubility in / Miscibility with water:

Fully miscible.

Partition coefficient: n-octanol/water:

Not determined.

Viscosity:
Dynamic:

Not determined.

Kinematic:

Not determined.

Solvent content:
Water:

95.0 %

Solids content:

5.0 %

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.

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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Safety data sheet

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Trade name: RIDA®GENE Helicobacter pylori Internal Control DNA

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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** 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:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 15.02.2022

Version number 3.0

Revision: 15.02.2022

Trade name: RIDA®GENE Helicobacter pylori Internal Control DNA

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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
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Trade name: RIDA®GENE Helicobacter pylori Internal Control DNA

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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:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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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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Safety data sheet

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Version number 2.0

Revision: 15.02.2022

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

1.1 Product identifier

Trade name: **RIDA®GENE Helicobacter pylori No Template Control**

Article number: PGZ2305NC

CAS Number:

7732-18-5

EC number:

231-791-2

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

The substance 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

3.1 Chemical characterisation: Substances

CAS No. Description

7732-18-5 water, distilled, conductivity or of similarpurity

Identification number(s)

EC number: 231-791-2

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.

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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: 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.

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

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: Not required.

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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Trade name: RIDA®GENE Helicobacter pylori No Template Control

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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.

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:**

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

pH-value: 7

Change in condition

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

Flash point: Not applicable.

Flammability (solid, gas): Not applicable.

Decomposition temperature: Not determined.

Auto-ignition temperature: Not determined.

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 g/cm³
Relative density Not determined.
Vapour density Not determined.
Evaporation rate Not determined.

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Trade name: RIDA®GENE Helicobacter pylori No Template Control

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Solubility in / Miscibility with water:

Fully miscible.

Partition coefficient: n-octanol/water:

Not determined.

Viscosity:
Dynamic at 20 °C:

0.952 mPas

Kinematic:

Not determined.

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.

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.

Additional ecological information:
General notes: Not hazardous for water.

12.5 Results of PBT and vPvB assessment
PBT: Not applicable.

vPvB: Not applicable.

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