

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.02.2013

Version number 1

Revision: 12.02.2013

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

- **Product identifier**
- **Trade name:** RIDA®QUICK Clostridium difficile GDH Reagent A
- **Article number:** N0703P01
- **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*
- **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](mailto:info@r-biopharm.de)
- **Emergency telephone number:** FE 0049-6151-8102-0

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

*Eye Irrit. 2 H319 Causes serious eye irritation.*

- 
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
  - **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.*

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  - **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**  
*The product is classified and labelled according to the CLP regulation.*
  - **Hazard pictograms** GHS07
  - **Signal word** Warning
  - **Hazard statements**  
*H319 Causes serious eye irritation.*
  - **Precautionary statements**
    - P280 *Wear protective gloves/protective clothing/eye protection/face protection.*
    - P264 *Wash thoroughly after handling.*
    - P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
    - P337+P313 *If eye irritation persists: Get medical advice/attention.*
  - **Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **Chemical characterization:** *Mixtures*
- **Description:** *Mixture of substances with nonhazardous additions.*

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**· Dangerous components:**

Polyethylene glycol octylphenol ether

0.1-1%

☒ Xn R22; ☒ Xi R41; ☒ N R51/53

☒ Eye Dam. 1, H318; ☒ Aquatic Chronic 2, H411; ☒ Acute Tox. 4, H302

**· Additional information:** For the wording of the listed risk phrases refer to section 16.**4 First aid measures****· 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.**· Information for doctor:****· Most important symptoms and effects, both acute and delayed** No further relevant information available.**· Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.**5 Firefighting measures****· Extinguishing media****· Suitable extinguishing agents:**CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.**· Special hazards arising from the substance or mixture** No further relevant information available.**· Advice for firefighters****· Protective equipment:** No special measures required.**6 Accidental release measures****· Personal precautions, protective equipment and emergency procedures** Wear protective clothing.**· Environmental precautions:**

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

**· Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

**· 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.

**7 Handling and storage****· Handling:****· Precautions for safe handling** Open and handle receptacle with care.**· Information about fire - and explosion protection:** No special measures required.**· 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.**· Specific end use(s)** No further relevant information available.

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### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **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:**  
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.
- **Eye protection:** Goggles recommended during refilling

### 9 Physical and chemical properties

- |  |   |
|--|---|
| · <b>Information on basic physical and chemical properties</b> |   |
| · <b>General Information</b>                                   |   |
| · <b>Appearance:</b>   |   |
| Form:  | Fluid   |
| Colour:  | Blue  |
| · <b>Odour:</b>  | Characteristic                                |
| · <b>Odour threshold:</b>                                      | Not determined.                               |
| · <b>pH-value:</b>   | Not determined.                               |
| · <b>Change in condition</b>                                   |   |
| Melting point/Melting range:                                   | Undetermined.                                 |
| Boiling point/Boiling range:                                   | 100 °C  |
| · <b>Flash point:</b>  | Not applicable.                               |
| · <b>Flammability (solid, gaseous):</b>                        | Not applicable.                               |
| · <b>Ignition temperature:</b>                                 |   |
| Decomposition temperature:                                     | Not determined.                               |
| · <b>Self-igniting:</b>  | Product is not selfigniting.                  |
| · <b>Danger of explosion:</b>                                  | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                                     |   |
| Lower:   | Not determined.                               |
| Upper:   | Not determined.                               |

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· <b>Vapour pressure at 20 °C:</b>	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.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	0.0 %
<b>Water:</b>	96.6 %
· <b>Solids content:</b>	2.4 %
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

**26628-22-8 sodium azide**

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

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Autoclave or dispose as hazardous waste.  
Disposal must be made according to official regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### 14 Transport information

- |  |  |
|--|--|
| · <b>UN-Number</b>   | Void   |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void   |
| · <b>UN proper shipping name</b>   | Void   |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void   |
| · <b>Transport hazard class(es)</b>  | Void   |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void   |
| · <b>Class</b>   | Void   |
| · <b>Packing group</b>   | Void   |
| · <b>ADR, IMDG, IATA</b>   | Void   |
| · <b>Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>   | No   |
| · <b>Special precautions for user</b>  | Not applicable.                                      |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.                                      |
| · <b>Transport/Additional information:</b>                                       | Not dangerous according to the above specifications. |
| · <b>UN "Model Regulation":</b>  | -  |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Waterhazard class:** Water hazard class 2 (Self-assessment): hazardous for water.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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## 16 Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Relevant phrases**

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H411 Toxic to aquatic life with long lasting effects.

R22 Harmful if swallowed.

R41 Risk of serious damage to eyes.

R51/53 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:**

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 Harmonized System of Classification and Labelling of Chemicals

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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