

29.01.2018

### Kit Components

Product code	Description
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<b>108230</b>	<b>DiaCidel</b>
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Components:

2035M	DiaCidel Wash Solution
2036M	DiaCidel Elution Solution
2037M	DiaCidel Buffer Solution

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 29.01.2018

Version number 4

Revision: 29.01.2018

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

### 1.1 Product identifier

Trade name: **DiaCidel Wash Solution**

Id-N° 108230

Bio-Rad MSDS Number: 2035M

Article number: 15910

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the mixture

In vitro diagnostic medical device or component.

### 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

DiaMed GmbH

Pra Rond 23

CH-1785 Cressier FR

(Switzerland/Schweiz/Suisse/Svizzera)

Tel: +41 (0)26 674 51 11

Fax: +41 (0)26 674 51 45

Further information obtainable from: [fds-msds.ch@bio-rad.com](mailto:fds-msds.ch@bio-rad.com)

### 1.4 Emergency telephone number: CHEMTREC UK (London) +(44)-870-8200418

## 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.

### 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 listed below with nonhazardous additions.

Dangerous components:

CAS: 26628-22-8

EINECS: 247-852-1

Index number: 011-004-00-7

Sodium Azide

Acute Tox. 2, H300; Acute Tox. 1, H310

Aquatic Acute 1, H400; Aquatic Chronic 1, H410

0.9%

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· **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:** Generally the product does not irritate the skin.
  - **After eye contact:** Rinse opened eye for several minutes under running water.
- **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:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
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** Not required.
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
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:** see related package insert.
- **7.3 Specific end use(s)** No further relevant information available.

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Trade name: **DiaCidel Wash Solution**

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## 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:**

#### 26628-22-8 Sodium Azide

WEL	Short-term value: 0.3 mg/m <sup>3</sup> Long-term value: 0.1 mg/m <sup>3</sup> (as NaN <sub>3</sub> ), 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:**

The usual precautionary measures are to be adhered to when handling chemicals.

· **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.

· **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:** Safety glasses

· **Body protection:** Protective work clothing

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

· **General Information**

· **Appearance:**

· **Form:**

Liquid

· **Colour:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **pH-value at 20 °C:** 6.8

· **Change in condition**

· **Melting point/freezing point:** Undetermined.

· **Initial boiling point and boiling range:** 100 °C

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

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· Ignition temperature:	
· 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:	23hPa
· Density:	Not determined.
· Relative density	Not determined.
· 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:	
· Water:	78.3%
· 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.

· <b>LD/LC50 values relevant for classification:</b>			
<b>26628-22-8 Sodium Azide</b>			
Oral	LD50	27 mg/kg (rat)	
Dermal	LD50	20 mg/kg (rabbit)	

- **Primary irritant effect:**
  - **Skin corrosion/irritation**  
Based on available data, the classification criteria are not met.

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- **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:** No further relevant information available.
- **CMR effects (carcinogenity, 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:**  
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.  
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.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
  - **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN-Number</b>               |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |
| · <b>14.2 UN proper shipping name</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |

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· <b>14.3 Transport hazard class(es)</b>	
· ADR, ADN, IMDG, IATA	
· Class	Void
· <b>14.4 Packing group</b>	
· ADR, IMDG, IATA	Void
· <b>14.5 Environmental hazards:</b>	
· Marine pollutant:	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Not dangerous according to the above specifications.
· <b>UN "Model Regulation":</b>	Void

## SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **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.
  - **Directive 2012/18/EU**
    - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
    - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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:**  
DiaMed GmbH  
Pra Rond 23  
CH-1785 Cressier FR  
(Switzerland/Schweiz/Suisse/Svizzera)
- **Abbreviations and acronyms:**  
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)

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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 – Category 2

Acute Tox. 1: Acute toxicity – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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## according to 1907/2006/EC, Article 31

Printing date 29.01.2018

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Revision: 29.01.2018

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

- **1.1 Product identifier**
  - Trade name: **DiaCidel Elution Solution**
  - Id-N° 108230
  - Bio-Rad MSDS Number: 2036M
  - Article number: 15920
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
  - **Application of the substance / the mixture**  
In vitro diagnostic medical device or component.
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
DiaMed GmbH  
Pra Rond 23  
CH-1785 Cressier FR  
(Switzerland/Schweiz/Suisse/Svizzera)  
Tel: +41 (0)26 674 51 11  
Fax: +41 (0)26 674 51 45
  - **Further information obtainable from:** fds-msds.ch@bio-rad.com
- **1.4 Emergency telephone number:** CHEMTREC UK (London) +(44)-870-8200418

### 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 listed below 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:** Generally the product does not irritate the skin.
  - **After eye contact:** Rinse opened eye for several minutes under running water.
  - **After swallowing:** If symptoms persist consult doctor.

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- **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.  
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** Not required.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.
- **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:** see related package insert.
- **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
  - **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
    - **Additional information:** The lists valid during the making were used as basis.

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## 8.2 Exposure controls

### Personal protective equipment:

#### General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

#### Respiratory protection: Not required.

#### Protection of hands:



Protective gloves

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

#### 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: Safety glasses

#### Body protection: Protective work clothing

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

##### Appearance:

##### Form:

Liquid

##### Colour:

Yellow

##### Odour:

Characteristic

##### Odour threshold:

Not determined.

pH-value at 20 °C: 2.3

#### Change in condition

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: 100 °C

Flash point: Not applicable.

Flammability (solid, gas): Not applicable.

Ignition temperature:

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: 23hPa

Density: Not determined.

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<ul style="list-style-type: none"> <li>· <b>Relative density</b></li> <li>· <b>Vapour density</b></li> <li>· <b>Evaporation rate</b></li> </ul>	<ul style="list-style-type: none"> <li>Not determined.</li> <li>Not determined.</li> <li>Not determined.</li> </ul>
<ul style="list-style-type: none"> <li>· <b>Solubility in / Miscibility with water:</b></li> </ul>	<ul style="list-style-type: none"> <li>Fully miscible.</li> </ul>
<ul style="list-style-type: none"> <li>· <b>Partition coefficient: n-octanol/water:</b></li> </ul>	<ul style="list-style-type: none"> <li>Not determined.</li> </ul>
<ul style="list-style-type: none"> <li>· <b>Viscosity:</b> <ul style="list-style-type: none"> <li>· <b>Dynamic:</b></li> <li>· <b>Kinematic:</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Not determined.</li> <li>Not determined.</li> </ul>
<ul style="list-style-type: none"> <li>· <b>Solvent content:</b> <ul style="list-style-type: none"> <li>· <b>Water:</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>97.7%</li> </ul>
<ul style="list-style-type: none"> <li>· <b>Solids content:</b></li> </ul>	<ul style="list-style-type: none"> <li>0.0%</li> </ul>
<ul style="list-style-type: none"> <li>· <b>9.2 Other information</b></li> </ul>	<ul style="list-style-type: none"> <li>No further relevant information available.</li> </ul>

## 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:** No further relevant information available.
  - **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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Trade name: **DiaCidel Elution Solution**

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## 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:** Generally not hazardous for water
- **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

## SECTION 14: Transport information

- |                                                                                  |                                                      |
|----------------------------------------------------------------------------------|------------------------------------------------------|
| · <b>14.1 UN-Number</b>                                                          |                                                      |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Void                                                 |
| · <b>14.2 UN proper shipping name</b>                                            |                                                      |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Void                                                 |
| · <b>14.3 Transport hazard class(es)</b>                                         |                                                      |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    |                                                      |
| · <b>Class</b>                                                                   | Void                                                 |
| · <b>14.4 Packing group</b>                                                      |                                                      |
| · <b>ADR, IMDG, IATA</b>                                                         | Void                                                 |
| · <b>14.5 Environmental hazards:</b>                                             |                                                      |
| · <b>Marine pollutant:</b>                                                       | No                                                   |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable.                                      |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.                                      |
| · <b>Transport/Additional information:</b>                                       | Not dangerous according to the above specifications. |
| · <b>UN "Model Regulation":</b>                                                  | Void                                                 |

## SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Labelling according to Regulation (EC) No 1272/2008** Void

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- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Directive 2012/18/EU**
  - **Named dangerous substances - ANNEX I** hydrogen chloride
- **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:**

DiaMed GmbH  
Pra Rond 23  
CH-1785 Cressier FR  
(Switzerland/Schweiz/Suisse/Svizzera)

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative

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

GB

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 29.01.2018

Version number 4

Revision: 29.01.2018

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

#### 1.1 Product identifier

Trade name: **DiaCidel Buffer Solution**

Id-N° 108230

Bio-Rad MSDS Number: 2037M

Article number: 15930

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the mixture

In vitro diagnostic medical device or component.

#### 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

DiaMed GmbH

Pra Rond 23

CH-1785 Cressier FR

(Switzerland/Schweiz/Suisse/Svizzera)

Tel: +41 (0)26 674 51 11

Fax: +41 (0)26 674 51 45

Further information obtainable from: [fds-msds.ch@bio-rad.com](mailto:fds-msds.ch@bio-rad.com)

#### 1.4 Emergency telephone number: CHEMTREC UK (London) +(44)-870-8200418

### 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

Additional information:

Safety data sheet available on request.

#### 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 listed below with nonhazardous additions.

Dangerous components:

CAS: 77-86-1

trometamol

1.2%

EINECS: 201-064-4

⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335

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:

In case of unconsciousness place patient stably in side position for transportation.

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**Trade name: DiaCidel Buffer Solution**

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- **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:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
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** Not required.
- **6.2 Environmental precautions:**  
No special measures required.  
Do not allow product to reach sewage system or any water course.
- **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

- **Handling:**
  - **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:** see related package insert.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
  - **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
    - **Additional information:** The lists valid during the making were used as basis.

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Trade name: **DiaCidel Buffer Solution**

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## 8.2 Exposure controls

### Personal protective equipment:

#### General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.

#### Protection of hands:



Protective gloves

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

#### 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: Safety glasses

#### Body protection: Protective work clothing

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

##### Appearance:

##### Form:

Liquid

##### Colour:

Clear

##### Odour:

Odourless

##### Odour threshold:

Not determined.

pH-value at 20 °C: 9.1

#### Change in condition

##### Melting point/freezing point:

Undetermined.

##### Initial boiling point and boiling range:

Undetermined.

Flash point: Not applicable.

Flammability (solid, gas): Not applicable.

#### Ignition temperature:

##### 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: 23hPa

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· <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</b>	
· <b>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>Water:</b>	91.7%
· <b>Solids content:</b>	0.0%
· <b>9.2 Other information</b>	No further relevant information available.

## SECTION 10: Stability and reactivity

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

## SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.

· <b>LD/LC50 values relevant for classification:</b>		
<b>26628-22-8 Sodium Azide</b>		
Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

- **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:** No further relevant information available.
  - **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.

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- **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:** Generally not hazardous for water
- **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**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
  - **Uncleaned packaging:**
    - **Recommendation:** Disposal must be made according to official regulations.

## SECTION 14: Transport information

- |                                                                                  |                                                      |
|----------------------------------------------------------------------------------|------------------------------------------------------|
| · <b>14.1 UN-Number</b>                                                          |                                                      |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Void                                                 |
| · <b>14.2 UN proper shipping name</b>                                            |                                                      |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    | Void                                                 |
| · <b>14.3 Transport hazard class(es)</b>                                         |                                                      |
| · <b>ADR, ADN, IMDG, IATA</b>                                                    |                                                      |
| · <b>Class</b>                                                                   | Void                                                 |
| · <b>14.4 Packing group</b>                                                      |                                                      |
| · <b>ADR, IMDG, IATA</b>                                                         | Void                                                 |
| · <b>14.5 Environmental hazards:</b>                                             |                                                      |
| · <b>Marine pollutant:</b>                                                       | No                                                   |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable.                                      |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.                                      |
| · <b>Transport/Additional information:</b>                                       | Not dangerous according to the above specifications. |

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· UN "Model Regulation":	Void
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### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Labelling according to Regulation (EC) No 1272/2008** Void
    - **Hazard pictograms** Void
    - **Signal word** Void
    - **Hazard statements** Void
  - **Directive 2012/18/EU**
    - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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.

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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)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- **\* Data compared to the previous version altered.**

GB