

SAFETY DATA SHEET

Revision date 22-Jun-2023

Revision Number 1

Section 1: Identification

Product identifier

Product Name Quality Control - DiaMed GmbH IVD MD

Catalogue Number(s) 009321, 009322, 009323, 009324, 009325, 009326, 009327, 009328, 009925, 009930, 009948, 814171100, 814172100

Other means of identification

Safety data sheet number 2711M

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Uses advised against No information available

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer

DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
Switzerland/Schweiz/Suisse/Svizzera)
e-mail: fds-msds.ch@bio-rad.com

Legal Entity / Contact Address

Bio-Rad Laboratories Pty Ltd
189 Bush Road
Albany Auckland
New Zealand

Technical Service +64 9 415 2280 or 0508 805 500
sales.nz@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC New Zealand: 64-98010034

GHS Classification

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

Label elements

Hazard statements

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

Other hazards which do not result in classification

Contains animal source material. (Cattle).
Contains human source material and / or potentially infectious components

Section 3: Composition/information on ingredients

The product contains no substances which at their given concentration, are considered to be hazardous to health

| Chemical name | CAS No | Weight-% |
|---------------------------|-------------|----------|
| Non-hazardous ingredients | Proprietary | Balance |

Section 4: First-aid measures

Description of first aid measures

| | |
|--------------|--|
| Inhalation | Remove to fresh air. |
| Eye contact | Contains human source material and / or potentially infectious components. Call a doctor. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. |
| Skin contact | Wash with soap and water. |
| Ingestion | Contains human source material and / or potentially infectious components. Call a doctor. |

Most important symptoms and effects, both acute and delayed

| | |
|----------|---------------------------|
| Symptoms | No information available. |
|----------|---------------------------|

Indication of any immediate medical attention and special treatment needed

| | |
|-----------------|--|
| Note to doctors | Contains human source material and / or potentially infectious components. |
|-----------------|--|

Section 5: Fire-fighting measures

Suitable Extinguishing Media

| | |
|--------------------------------|---|
| Suitable Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Large Fire | CAUTION: Use of water spray when fighting fire may be inefficient. |
| Unsuitable extinguishing media | Do not scatter spilled material with high pressure water streams. |

Specific hazards arising from the chemical

| | |
|--|---------------------------|
| Specific hazards arising from the chemical | No information available. |
|--|---------------------------|

Special protective actions for fire-fighters

| | |
|--|---|
| Special protective equipment and precautions for fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. |
|--|---|

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

| | |
|--------------------------|---|
| Personal precautions | Ensure adequate ventilation. |
| For emergency responders | Use personal protection recommended in Section 8. |

Environmental precautions

| | |
|---------------------------|---|
| Environmental precautions | See Section 12 for additional Ecological Information. |
|---------------------------|---|

Methods and material for containment and cleaning up

Methods for containment Do not allow into any sewer, on the ground or into any body of water.

Methods for cleaning up Use: Disinfectant. Clean contaminated surface thoroughly.

Precautions to prevent secondary hazards

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

Section 7: Handling and storage**Precautions for safe handling**

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

General hygiene considerations Follow universal and standard precautions for handling potentially infectious materials.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

Incompatible materials None known based on information supplied.

Section 8: Exposure controls/personal protection**Control parameters**

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Environmental exposure controls No information available.

Section 9: Physical and chemical properties**Information on basic physical and chemical properties**

| | |
|------------------------|--------------------------|
| Physical state | Liquid |
| Appearance | No information available |
| Colour | No information available |
| Odour | Odourless. |
| Odour threshold | No information available |

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|---|---------------------------|-------------------------|
| pH | 6.9 - 7.5 | None known |
| Melting point / freezing point | No data available | None known |
| Boiling point / boiling range | No data available | None known |
| Flash point | No data available | None known |
| Evaporation rate | No data available | None known |
| Flammability (solid, gas) | No data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive limits | No data available | |
| Lower flammability or explosive limits | No data available | |
| Vapour pressure | No data available | None known |
| Vapour density | No data available | None known |
| Relative density | No data available | None known |
| Water solubility | No data available | Miscible in water |
| Solubility(ies) | No data available | None known |
| Partition coefficient | No data available | None known |
| Autoignition temperature | No data available | None known |
| Decomposition temperature | | None known |
| Kinematic viscosity | No data available | None known |
| Dynamic viscosity | No data available | None known |
| Explosive properties | No information available. | |
| Oxidising properties | No information available. | |
| <u>Other information</u> | | |
| Softening point | No information available | |
| Molecular weight | No information available | |
| VOC content | No information available | |
| Liquid Density | No information available | |
| Bulk density | No information available | |
| Particle characteristics | No information available | |

Section 10: Stability and reactivity

Reactivity

| | |
|-------------------|---------------------------|
| Reactivity | No information available. |
|-------------------|---------------------------|

Chemical stability

| | |
|------------------|---------------------------------|
| Stability | Stable under normal conditions. |
|------------------|---------------------------------|

Explosion data

| | |
|---|-------|
| Sensitivity to mechanical impact | None. |
|---|-------|

| | |
|--|-------|
| Sensitivity to static discharge | None. |
|--|-------|

Possibility of hazardous reactions

| | |
|---|-------------------------------|
| Possibility of hazardous reactions | None under normal processing. |
|---|-------------------------------|

Conditions to avoid

| | |
|----------------------------|---|
| Conditions to avoid | None known based on information supplied. |
|----------------------------|---|

Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

Section 11: Toxicological information**Acute toxicity****Information on likely routes of exposure****Product Information**

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms No information available.

Acute toxicity**Numerical measures of toxicity****Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Data used to identify the health effects Refer to Section 16 for Key literature references and sources for data used to compile the SDS.

Section 12: Ecological information

Ecotoxicity

| | |
|--------------------------------------|--|
| Aquatic ecotoxicity | The environmental impact of this product has not been fully investigated. |
| Unknown aquatic toxicity | 0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment. |
| Terrestrial ecotoxicity | There is no data for this product. |
| Persistence and degradability | No information available. |

Bioaccumulative potential

| | |
|------------------------|------------------------------------|
| Bioaccumulation | There is no data for this product. |
|------------------------|------------------------------------|

Mobility in soil

| | |
|-----------------|---------------------------|
| Mobility | No information available. |
|-----------------|---------------------------|

Other adverse effects

No information available.

Section 13: Disposal considerations

Waste treatment methods

| | |
|--|---|
| Waste from residues/unused products | Not applicable. Not Hazardous. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
| Contaminated packaging | Not applicable. Not Hazardous. |

Section 14: Transport information

| | |
|--------------------|---------------|
| <u>IATA</u> | Not regulated |
|--------------------|---------------|

| | |
|--------------------|---------------|
| <u>IMDG</u> | Not regulated |
|--------------------|---------------|

Transport in bulk according to Annex II of MARPOL and the IBC Code
No information available

Special precautions for user
Please refer to the applicable dangerous goods regulations for additional information

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

EPA New Zealand HSNO approval code or group standard To be determined

National regulations There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

Certified handlers, tracking and controlled substance license requirements Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information
Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information
Controlled substance licenses are required to possess certain explosives, vertebrate toxic agents and fumigants. See Part 7 of the Health and Safety at Work Regulation 2017 for more information

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

| | |
|----------------------|---|
| NZIoC | Contact supplier for inventory compliance status. |
| TSCA | Contact supplier for inventory compliance status. |
| DSL/NDSL | Contact supplier for inventory compliance status. |
| EINECS/ELINCS | Contact supplier for inventory compliance status. |
| ENCS | Contact supplier for inventory compliance status. |
| IECSC | Contact supplier for inventory compliance status. |
| KECL | Contact supplier for inventory compliance status. |
| PICCS | Contact supplier for inventory compliance status. |
| AICS | Contact supplier for inventory compliance status. |

Legend:

NZIoC - New Zealand Inventory of Chemicals
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

Section 16: Other information

Revision date 22-Jun-2023

Revision Note Significant changes throughout SDS. Review all sections.

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

| | | | |
|----------------|-----------------------------|-------------|----------------------------------|
| TWA | TWA (time-weighted average) | STEL | STEL (Short Term Exposure Limit) |
| Ceiling | Maximum limit value | * | Skin designation |
| C | Carcinogen | | |

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
National Institute of Technology and Evaluation (NITE)
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Disclaimer

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End of Safety Data Sheet