



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 15-Sep-2023

Revision Number 1.4

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

1.1. Product identifier

Product Name	Exact Diagnostics C. difficile Verification Bundle
Catalogue Number(s)	CDFB200, CDFP200
Nanoforms	Not applicable
Pure substance/mixture	Mixture

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

Recommended use	In vitro diagnostic
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters

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

Manufacturer

Exact Diagnostics
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104
USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd
The Junction
Station Road
Watford, WD17 1ET
UK

Bio-Rad Laboratories Pvt. Ltd.
Bio-Rad House
86-87, Udyog Vihar Phase IV Gurgaon
122005
Haryana India

Bio-Rad Laboratories (Pty) Ltd.
34 Bolton Road
Parkwood, Johannesburg 2193
South Africa

For further information, please contact

Technical Service	00800 00246 723 Ireland: Techsupport.UK@bio-rad.com India: support.india@bio-rad.com South Africa: cdg_techsupport_eemea@bio-rad.com
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1.4. Emergency telephone number

24 Hour Emergency Phone Number	CHEMTREC Ireland: 353-19014670 CHEMTREC India: 000-800-100-7141 CHEMTREC South Africa: 0-800-983-611
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

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

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. 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.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

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

SECTION 5: Firefighting measures

5.1. 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.

5.2. Special hazards arising from the substance or mixture**Specific hazards arising from the chemical**

No information available.

5.3. Advice for firefighters**Special protective equipment and precautions for fire-fighters**

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****Personal precautions**

Ensure adequate ventilation.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions**Environmental precautions**

See Section 12 for additional Ecological Information.

6.3. 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.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections**Reference to other sections**

See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Ensure adequate ventilation.

General hygiene considerations

Follow universal and standard precautions for handling potentially infectious materials.

7.2. Conditions for safe storage, including any incompatibilities**Storage Conditions**

Store according to product and label instructions.

7.3. Specific end use(s)**Risk Management Methods (RMM)**

The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. 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.

Derived No Effect Level (DNEL) No information available.
Predicted No Effect Concentration (PNEC)

8.2. Exposure controls**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.

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

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state Liquid
Appearance Clear
Colour clear
Odour No information available.
Odour threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Boiling point / boiling range	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	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	7.8-8.2	
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known

Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information**9.2.1. Information with regards to physical hazard classes**

Not applicable

9.2.2. Other safety characteristics

No information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Avoid contact with metals. This product contains Sodium azide. Sodium azide can react with Copper, Brass, Lead, and solder in piping systems to form explosive compounds and toxic gases.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****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.
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Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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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.
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Serious eye damage/eye irritation	No information available.
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Respiratory or skin sensitisation	No information available.
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Germ cell mutagenicity	No information available.
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Carcinogenicity	No information available.
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Reproductive toxicity	No information available.
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STOT - single exposure	No information available.
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STOT - repeated exposure	No information available.
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Aspiration hazard	No information available.
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11.2. Information on other hazards**11.2.1. Endocrine disrupting properties**

Endocrine disrupting properties	This product does not contain any known or suspected endocrine disruptors.
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11.2.2. Other information

Other adverse effects	No information available.
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SECTION 12: Ecological information**12.1. Toxicity**

Ecotoxicity	The environmental impact of this product has not been fully investigated.
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Unknown aquatic toxicity	Contains 0 % of components with unknown hazards to the aquatic environment.
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12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. Flush pipes with water frequently if discarding solutions containing Sodium azide into metal piping systems.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated

14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations****Germany**

 Water hazard class (WGK) non-hazardous to water (nwg)

European Union

 Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment**Chemical Safety Report**

No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA Ceiling	TWA (time-weighted average) Maximum limit value	STEL *	STEL (Short Term Exposure Limit) Skin designation
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Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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)
 European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
 European Chemicals Agency (ECHA) (ECHA_API)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AELG(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

Revision Note Reviewed existing information and made minor updates

Revision date 15-Sep-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet