

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: UK REACH Regulations (SI 2019/758 as amended)

Revision date 15-Sep-2023 Revision Number 1.1

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

1.1. Product identifier

Product Name Exact Diagnostics SARS-CoV-2 Negative

Catalogue Number(s) COV000CE

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.

Manufacturer
Exact Diagnostics

1000 Alfred Nobel Drive 100 South Jones Street, Suite 100,

Hercules, CA 94547 Fort Worth, Texas 76104

USA USA

South Jones Street, Suite 100, The Junction

Station Road
Watford, WD17 1ET

**Legal Entity / Contact Address** 

Bio-Rad Laboratories Ltd

UK

For further information, please contact

**Technical Service** 00800 00246 723

Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

## **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

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

# 2.2. Label elements

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

#### **Hazard statements**

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

#### 2.3. Other hazards

## **SECTION 3: Composition/information on ingredients**

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#### 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

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK 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

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**

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## 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

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** No information available.

(PNEC)

8.2. Exposure controls

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Engineering controls No information available.

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.

## **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

Property Values Remarks • Method

Melting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

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 None known Kinematic viscosity No data available None known **Dvnamic 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 No data available Relative density None known

Bulk density

Liquid Density

No data available

No data available

Vapour density No data available None known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

#### 9.2. Other information

# **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

**Reactivity** No information available.

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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. Toxicological information

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 related to the physical, chemical and toxicological characteristics

**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.

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**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.

Other adverse effects No information available.

## **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

**Unknown aquatic toxicity**Contains 0 % of components with unknown hazards to the aquatic environment.

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

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

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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 numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

#### **IMDG**

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

**14.7 Maritime transport in bulk** No information available

according to IMO instruments

#### RID

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

## <u>ADR</u>

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot 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

### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

### **Persistent Organic Pollutants**

Not applicable

### **Export Notification requirements**

Not applicable

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#### Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

#### The Ozone-Depleting Substances Regulations 2015

Not applicable

#### The Biocidal Products Regulations 2001 (as amended)

Not applicable

## The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

#### Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

<u>International Inventories</u> Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report No information available

## **SECTION 16: Other information**

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#### 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

aarding to Degulation (EC) No. 1070/2009 [CLD]

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value \* Skin designation

+ Sensitisers

## 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) (AÉGL(s))

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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

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#### **Revision Note**

Reviewed existing information and made minor updates

This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended) 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

#### **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** 

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