

# SAFETY DATA SHEET

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

Revision date 12-Jan-2023 Revision Number 2

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

1.1. Product identifier

Pure substance/mixture

Product Name BioPlex 2200 SARS-CoV-2 IgG Reagent Pack

Mixture

Catalogue Number(s) 12014192

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

Recommended use In vitro diagnostic Restricted to professional users Use according to package label

instructions

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 <u>Manufacturer</u>

Bio-Rad Laboratories 6565-185th Ave NE Redmond, WA 98052

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

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

Chronic aquatic toxicity Category 3 - (H412)

2.2. Label elements

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#### **Hazard statements**

H412 - Harmful to aquatic life with long lasting effects

#### **Precautionary statements**

P501 - Dispose of contents/ container to an approved waste disposal plant

### 2.3. Other hazards

Contains animal source material. (Mouse). (Cattle). Harmful to aquatic life.

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

#### 3.1 Substances

Not applicable

#### 3.2 Mixtures

Component	Description
BEAD	One (1) 10 mL vial, containing dyed beads coated with RBD, S1, S2, nucleocapsid protein, Internal Standard(ISB), and Serum Verification (SVB), with glycerol and protein stabilizers (bovine) in a MOPS (3-[N-Morpholino] propanesulfonic acid) buffer. ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) are added as preservatives
CONJ	One (1) 5 mL vial, containing murine monoclonal anti-human IgG/phycoerythrin conjugate and murine antihuman FXIII/phycoerythrin conjugate in a phosphate buffer with protein stabilizers (bovine). ProClin 300 (≤ 0.3%) and sodium azide (< 0.1%) are added as preservatives
DIL	One (1) 10 mL vial, containing protein stabilizers (bovine and murine) in a triethanolamine buffer. ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%), and sodium azide (< 0.1%) are added as preservatives

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
1,2,3-Propanetriol 56-81-5	5 - 10	200-289-5	-	-	1	-	-
Sodium azide 26628-22-8	0.01 - 0.099	247-852-1	-	(EUH032) Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	-	-
5-Chloro-2-methyl-3( 2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothi azolone 55965-84-9	0.001 - 0.01	•	-	(EUH071) Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1C (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute	-	100	100

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	1 (H400)	
	Aquatic	
	Chronic 1	
	(H410)	

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#### 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.

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Eye contact

Consult a doctor.

Skin contact In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and

water.

Rinse mouth. Ingestion

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

No information available. **Symptoms** 

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

Note to doctors Treat symptomatically.

# **SECTION 5: Firefighting measures**

5.1. Extinguishing media

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment.

CAUTION: Use of water spray when fighting fire may be inefficient. Large Fire

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.

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**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** Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

**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** Wash hands before breaks and immediately after handling the product.

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**

Chemical name	United Kingdom
1,2,3-Propanetriol	TWA: 10 mg/m <sup>3</sup>
56-81-5	STEL: 30 mg/m <sup>3</sup>
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>
26628-22-8	STEL: 0.3 mg/m <sup>3</sup>
	Sk*

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 No special protective equipment required.

Skin and body protection No special protective equipment required.

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.

# **SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and chemical properties

**Physical state** Liquid

**Appearance** Plastic cartridge containing various bottles Dilute bead suspension in aqueous solution

Colour light brown light pink light vellow Odour No information available. **Odour threshold** No information available

Values Remarks • Method Property

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 No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known **Autoignition temperature** 200 °C None known **Decomposition temperature** None known

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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 Partially miscible

No data available Solubility(ies) None known Partition coefficient No data available None known No data available Vapour pressure None known No data available Relative density None known

**Bulk density** No data available **Liquid Density** No data available

Vapour density No data available None known

Particle characteristics

No information available Particle Size Particle Size Distribution No 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**

No information available

1.20443 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

1.20443 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

9.73171 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

9.73171 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour).

1.20443 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

**Component Information** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
1,2,3-Propanetriol	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 2.75 mg/L (Rat) 4 h
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit)	0.054 - 0.52 mg/L (Rat) 4 h

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5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with			
2-methyl-3(2H)-isothiazolone			

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.

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.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
1,2,3-Propanetriol	_	LC50: 51 - 57mL/L (96h,		_
1,2,5-1 Topanethol	_	Oncorhynchus mykiss)	_	_
Sodium azide	-	LC50: =0.8mg/L (96h,	-	-
		Oncorhynchus mykiss)		
		LC50: =0.7mg/L (96h,		
		Lepomis macrochirus)		
		LC50: =5.46mg/L (96h,		
		Pimephales promelas)		

#### 12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

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#### **Bioaccumulation**

**Component Information** 

Chemical name	Partition coefficient
1,2,3-Propanetriol	-1.75
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	0.7
2-methyl-3(2H)-isothiazolone	

#### 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.

Chemical name	PBT and vPvB assessment
1,2,3-Propanetriol	The substance is not PBT / vPvB
Sodium azide	The substance is not PBT / vPvB
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	The substance is not PBT / vPvB
2-methyl-3(2H)-isothiazolone	

#### 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

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**

14.1 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 No

14.7 Maritime transport in bulk No info according to IMO instruments

No information available

RID

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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
440 Ourselel Deservitions for House	
14.6 Special Precautions for Users	

# **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

#### 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)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	PT02 - Disinfectants and algaecides not intended for direct
2-methyl-3(2H)-isothiazolone - 55965-84-9	application to humans or animals
	PT06 - Preservatives for products during storage
	PT13 - Working or cutting fluid preservatives
	PT04 - Food and feed area
	PT11 - Preservatives for liquid-cooling and processing
	systems
	PT12 - Slimicides

# 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

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**Chemical Safety Report** 

No information available

#### **SECTION 16: Other information**

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

#### Full text of H-Statements referred to under section 3

EUH032 - Contact with acids liberates very toxic gas

EUH071 - Corrosive to the respiratory tract

H300 - Fatal if swallowed

H301 - Toxic if swallowed

H310 - Fatal in contact with skin

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H330 - Fatal if inhaled

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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) (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)

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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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