



# 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

**Product Name** BioPlex 2200 Anti-CCP Control Set

**Catalogue Number(s)** 6633230

**Pure substance/mixture** Mixture

### 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

#### **Manufacturer**

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

<b>Chronic aquatic toxicity</b>	Category 3 - (H412)
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### 2.2. Label elements

**Hazard statements**

H412 - Harmful to aquatic life with long lasting effects

**Precautionary statements**

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

P280 - Wear protective gloves/protective clothing/eye protection/face protection

**2.3. Other hazards**

Contains components derived from human urine. Harmful to aquatic life.

**SECTION 3: Composition/information on ingredients****3.1 Substances**

Not applicable

**3.2 Mixtures**

Component	Description
Positive Control	For the BioPlex 2200 Anti-CCP Positive Control – Two (2), 1.5 mL vials. The positive controls are provided in a human serum matrix made from defibrinated plasma with added antibodies to CCP derived from human disease state plasma. All Controls contain preservatives including $\leq 0.3\%$ ProClin 300, $< 0.1\%$ sodium azide and $\leq 0.1\%$ sodium benzoate
Negative Control	BioPlex 2200 Anti-CCP Negative Control – Two (2), 1.5 mL vials. The negative controls are provided in a human serum matrix made from defibrinated plasma. All controls contain preservatives including $\leq 0.3\%$ ProClin 300, $< 0.1\%$ sodium azide and $\leq 0.1\%$ sodium benzoate

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)
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)-isothiazolone 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 1 (H400) Aquatic Chronic 1 (H410)	-	100	100

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

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (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.
Skin contact	In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and water.
Ingestion	Contains human source material and / or potentially infectious components.

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

Symptoms	No information available.
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**4.3. Indication of any immediate medical attention and special treatment needed**

Note to doctors	Contains human source material and / or potentially infectious components.
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**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.
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**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.
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**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.
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**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.
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.
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**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.
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**7.3. Specific end use(s)**

Risk Management Methods (RMM)	The information required is contained in this Safety Data Sheet.
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**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure Limits**

Chemical name	United Kingdom
Sodium azide 26628-22-8	TWA: 0.1 mg/m <sup>3</sup> 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.
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Derived No Effect Level (DNEL)	No information available.
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Predicted No Effect Concentration (PNEC)	No information available.
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**8.2. Exposure controls**

Engineering controls	No information available.
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**Personal protective equipment**

Eye/face protection	No special protective equipment required.
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<b>Skin and body protection</b>	No special protective equipment required.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Liquid
<b>Appearance</b>	aqueous solution
<b>Colour</b>	amber
<b>Odour</b>	No information available.
<b>Odour threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point / boiling range</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	1010 °C	
<b>Decomposition temperature</b>		None known
<b>pH</b>		
<b>pH (as aqueous solution)</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	Miscible in water	
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Vapour pressure</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Bulk density</b>	No data available	
<b>Liquid Density</b>	No data available	
<b>Vapour density</b>	No data available	None known
<b>Particle characteristics</b>		
<b>Particle Size</b>	No information available	
<b>Particle Size Distribution</b>	No information available	

### 9.2. Other information

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

<b>Reactivity</b>	No information available.
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### 10.2. Chemical stability

<b>Stability</b>	Stable under normal conditions.
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### Explosion data

<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	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

2.5267 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

2.5267 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

2.5267 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

2.5267 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour).

2.5267 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium azide	= 27 mg/kg ( Rat )	= 20 mg/kg ( Rabbit )	0.054 - 0.52 mg/L ( Rat ) 4 h
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	= 53 mg/kg ( Rat )	= 87.12 mg/kg ( Rabbit )	-

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation** No information available.

<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitisation</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	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 0.0267 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
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

#### Bioaccumulation

#### Component Information

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

### 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
Sodium azide	The substance is not PBT / vPvB
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	The substance is not PBT / vPvB

**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 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****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 2-methyl-3(2H)-isothiazolone - 55965-84-9	PT02 - Disinfectants and algicides not intended for direct 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

**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****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) (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 date** 12-Jan-2023

**Revision Note** Reviewed existing information and made minor updates

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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**