

SAFETY DATA SHEET

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

Revision date 11-Jul-2024 Revision Number 3.2

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

1.1. Product identifier

Product Name BioPlex 2200 APLS IgG

Catalogue Number(s) 6651950

Pure substance/mixture Mixture

Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone

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

Recommended use Restricted to professional users Use according to package label instructions 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 Bio-Rad Laboratories 14620 NE N Woodinville Way Woodinville, WA 98072

USA

<u>Supplier</u> 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.

43 Bolton Road

Parkwood, Johannesburg 2192

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3 bld Raymond Poincaré 92430 Marnes-la-Coquette

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Phone: (33) 1-4795-6000

For further information, please contact

Technical Service 00800 00246 723

Ireland: Techsupport.UK@bio-rad.com India: support.india@bio-rad.com

South Africa: lsg_techsupport_eemea@bio-rad.com

1.4. Emergency telephone number

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

XGHS / BE Page 1/12

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Skin sensitisation	Category 1 - (H317)
Chronic aquatic toxicity	Category 3 - (H412)

2.2. Label elements

Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone



Signal word Warning

Hazard statements

H317 - May cause an allergic skin reaction

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

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

2.3. Other hazards

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

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 CL and ß2GPI; an Internal Standard bead(ISB), a Serum Verification bead (SVB), and a Reagent Blank bead (RBB) in a MOPS (3-[N-Morpholino] propanesulfonic acid) buffer supplemented with glycerol and protein stabilizers (porcine). ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives
CONJ	One (1) 5 mL vial, containing phycoerythrin conjugated murine monoclonal anti-human IgGantibody and phycoerythrin conjugated murine monoclonal anti-human FXIII antibody in MOPS(3-[N-Morpholino] propanesulfonic acid) buffer supplemented with protein stabilizers (bovine).ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives
DIL	One (1) 10 mL vial, containing buffer with protein stabilizers (bovine and murine). ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives

XGHS / BE Page 2/12

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	-	-	-	-	-
Sodium azide 26628-22-8	0.01 - 0.099	247-852-1 (011-004-00-7)	-	Acute Tox. 2 (H300) Acute Tox. 1 (H310) (EUH032) 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	0.01 - 0.099	(613-167-00-5)		Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Eye Irrit. 2 :: 0.06%<=C<0.6 % Skin Corr. 1C :: C>=0.6% Skin Irrit. 2 :: 0.06%<=C<0.6 % Skin Sens. 1A :: C>=0.0015% Eye Dam. 1 :: C>=0.6%	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 >= 0.1% (UK REACH Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

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

Consult a doctor.

Skin contact Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation

or allergic reactions see a doctor.

Ingestion Rinse mouth.

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

XGHS / BE Page 3/12

Symptoms Itching. Rashes. Hives.

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

Note to doctorsMay cause sensitisation in susceptible persons. Treat symptomatically.

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

Product is or contains a sensitiser. May cause sensitisation by skin contact.

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 Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal

protective equipment as required. Evacuate personnel to safe areas. Keep people away

from and upwind of spill/leak.

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

XGHS / BE Page 4/12

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

skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off

contaminated clothing and wash it before reuse.

General hygiene considerations Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. 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 ³
56-81-5	STEL: 30 mg/m ³
Sodium azide	TWA: 0.1 mg/m ³
26628-22-8	STEL: 0.3 mg/m ³
	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

(PNEC)

No information available.

8.2. Exposure controls

Engineering controlsNo 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.

exceeded or irritation is experienced, ventilation and evacuation may be required.

XGHS / BE Page 5/12

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Liquid Physical state

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

Colour light brown light pink light yellow

Odour No information available. Odour threshold No information available

Property Values Remarks • Method

Melting point / freezing point No data available None known Initial boiling point and boiling rangeNo data available None known **Flammability** 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

No data available Flash point None known

Autoignition temperature 392.8 °C

Decomposition temperature

7-8 No data available pH (as aqueous solution)

Kinematic viscosity No data available Dynamic viscosity No data available Water solubility No data available Solubility(ies) No data available Partition coefficient No data available Vapour pressure No data available No data available Relative density

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

No data available Relative vapour density 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

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge

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

None known

gases.

XGHS / BE Page 6/12 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 toxicological effects

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 May cause sensitisation by skin contact. Specific test data for the substance or mixture is

not available. Repeated or prolonged skin contact may cause allergic reactions with

susceptible persons (based on components).

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Acute toxicity

Numerical measures of toxicity

Component Information

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
5-Chloro-2-methyl-3(2H)-isothia zolone, 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/irritationNo information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation May cause an allergic skin reaction.

XGHS / BE Page 7/12

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 Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0.16994 % 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, 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

Bioaccumulation

Component Information

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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

XGHS / BE Page 8/12

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

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ΙΔ		Δ	

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards

Not regulated
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

IMDG

14.1 UN number or ID number
 14.2 UN proper shipping name
 14.3 Transport hazard class(es)
 14.4 Packing group
 14.5 Environmental hazards
 Not regulated Not regulated Not applicable

14.6 Special precautions for user

Special Provisions None

14.7 Maritime transport in bulk No information available according to IMO instruments

RID

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards

Not regulated
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

ADR

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
Not regulated
Not regulated
Not regulated

XGHS / BE Page 9/12

14.4 Packing group Not regulated14.5 Environmental hazards Not applicable

14.6 Special precautions for user

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 (SI 2015/483 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)
	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 and Explosive Precursors

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

XGHS / BE Page 10/12

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

H311 - Toxic in contact with skin

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H331 - Toxic 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 Sk* Skin designation

+ Sensitisers

Classification procedure Classification according to Regulation (EC) No. 1272/2008 [CLP]

CHOCOMOCAL CHOCOCA CHOCOCA CHOCOCA CHOCA C	
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)

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)

U.S. 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

XGHS / BE Page 11/12

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 11-Jul-2024

Revision Note Reformatted and updated existing information

This SDS 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

XGHS / BE Page 12/12