

SAFETY DATA SHEET

According to WHS Regulations

Revision date 11-Jul-2024 **Revision Number** 4.2

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

Product identifier

Product Name BioPlex 2200 APLS IgA Control Set

6632130 Catalogue Number(s)

Other means of identification

Pure substance/mixture Mixture

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Restricted to professional users

Use according to package label instructions

Uses advised against No information available

Details of manufacturer or importer

Corporate Headquarters Manufacturer Bio-Rad Laboratories Inc. **Bio-Rad Laboratories** 14620 NE N Woodinville Way 1000 Alfred Nobel Drive Hercules, CA 94547 Woodinville, WA 98072 USA USA

Legal Entity / Contact Address Bio-Rad Laboratories Pty Ltd u1A, 62 Ferndell Street, South Granville NSW 2142

Australia

For further information, please contact

Technical Service +61 2 9914 2800 or 1800 224 354

sales.australia@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Australia: 61-290372994

No information available Emergency telephone number

SECTION 2: Hazards identification

GHS Classification

Skin sensitisation Category 1 - (H317)

Label elements

Exclamation mark

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Signal word Warning

Hazard statements

H317 - May cause an allergic skin reaction

Precautionary Statements - Prevention

Avoid breathing dust/fume/gas/mist/vapours/spray

Contaminated work clothing should not be allowed out of the workplace

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

IF ON SKIN: Wash with plenty of water and soap

If skin irritation or rash occurs: Get medical advice/attention

Take off all contaminated clothing and wash it before reuse

Precautionary Statements - Disposal

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

Other hazards which do not result in classification

Harmful to aquatic life with long lasting effects Harmful to aquatic life

General Hazards

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

Substance

Not applicable

<u>Mixture</u>

Component	Description	
Positive Control BioPlex 2200 APLS IgA Positive Control – Four (4), 1.5 mL vials. The positive controls		
	human serum matrix made from defibrinated plasma with added IgA antibody to Cardiolipin (CL) and	
	Beta-2 Glycoprotein I (ß2GPI) derived from human disease state plasma. All Controls contain	
	preservatives including ≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate	
Negative Control	BioPlex 2200 APLS IgA Negative Control – Two (2), 1.5 mL vials. The negative controls are provided in a	
	human serum matrix made from defibri¬nated plasma. All controls contain preservatives including ≤	
	0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate	

Chemical name	CAS No.	Weight-%
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	55965-84-9	0.001 - 0.01
2-methyl-3(2H)-isothiazolone		
Non-hazardous ingredients	Proprietary	Balance

SECTION 4: First aid measures

Description of first aid measures

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

Emergency telephone number Poisons Information Centre, Australia: 13 11 26

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Poisons Information Centre, New Zealand: 0800 764 766

Inhalation Remove to fresh air.

Eye contact Contains human source material and / or potentially infectious components. 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. Wash skin with soap and water.

Ingestion Call a doctor. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

Indication of any immediate medical attention and special treatment needed

Note to doctors May cause sensitisation in susceptible persons. Treat symptomatically. Contains human

source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Suitable Extinguishing Media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical

Specific hazards arising from the

chemical

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

Special protective actions for fire-fighters

Special protective equipment for

fire-fighters

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

SECTION 6: Accidental release measures

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.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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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 Clean contaminated surface thoroughly. Use:. Disinfectant.

Precautions to prevent secondary hazards

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling

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 Follow universal and standard precautions for handling potentially infectious materials.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

Keep out of the reach of children. Store according to product and label instructions.

Incompatible materials Metals.

SECTION 8: Exposure controls/personal protection

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

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin and body protectionWear suitable protective clothing.

Hand protection Wear suitable gloves.

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.

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No information available. **Environmental exposure controls**

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid

Appearance aqueous solution

Colour amber

No information available. Odour No information available **Odour threshold**

Remarks • Method **Property** Values

pН

Melting point / freezing point No data available None known Initial boiling point and boiling rangeNo data available None known Flash point No data available None known **Evaporation rate** No 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

None known No data available Vapour pressure No data available None known Relative vapour density None known

Relative density

Water solubility Miscible in water

Solubility(ies) No data available None known **Partition coefficient** No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** None known

Kinematic viscosity No data available Dynamic viscosity No data available

Explosive properties Not applicable Not applicable **Oxidising properties**

Other information

Molecular weight Not applicable **VOC** content Not applicable

SECTION 10: Stability and reactivity

Reactivity

Reactivity No information available.

Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Possibility of hazardous reactions

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None known

None known

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.

Conditions to avoid

Conditions to avoidNone known based on information supplied.

Incompatible materials

Incompatible materials Metals.

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

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 Itching. Rashes. Hives.

Numerical measures of toxicity - Product Information

No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with			
2-methyl-3(2H)-isothiazolone			

See section 16 for terms and abbreviations

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

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation May cause sensitisation by skin contact.

Germ cell mutagenicityBased on available data, the classification criteria are not met.

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Based on available data, the classification criteria are not met. Carcinogenicity Reproductive toxicity Based on available data, the classification criteria are not met. STOT - single exposure Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. STOT - repeated exposure Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment.

Persistence and degradability

No information available. Persistence and degradability

Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

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

Mobility

Mobility in soil No information available. No information available. Mobility

Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

Disposal methods

Waste from residues/unused Flush pipes with water frequently if discarding solutions containing Sodium azide into metal products

piping systems. Dispose of in accordance with local regulations. Dispose of waste in

accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

UGHS / BE Page 7/9 ADG Not regulated

IMDG Not regulated

Not regulated

Transport in bulk according to Annex II of MARPOL and the IBC Code

No information available

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Australia

See section 8 for national exposure control parameters

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

No poisons schedule number allocated

International Inventories

Contact supplier for inventory compliance status

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 11-Jul-2024

Revision Note Reformatted and updated existing information.

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

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

C Carcinogen

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)

Environmental Protection Agency

Acute Exposure Guideline Level(s) (AEGL(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)

Japan GHS Classification

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

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

RTECS (Registry of Toxic Effects of Chemical Substances)

World Health Organization

Disclaimer

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End of Safety Data Sheet

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