



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Canada WHMIS 2015 which includes the amended Hazardous Products Act (HPA) and the Hazardous Products Regulation (HPR)

Revision date 11-Jul-2024

Revision Number 4.2

1. Identification

Product identifier

Product Name BioPlex 2200 APLS IgM Control Set

Other means of identification

Catalog Number(s) 6632030

Recommended use of the chemical and restrictions on use

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

Restrictions on use No information available

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer Address

Bio-Rad Laboratories
14620 NE N Woodinville Way
Woodinville, WA 98072
USA

Legal Entity / Contact Address

Bio-Rad Laboratories (Canada) Ltd.
2403 Guenette
Montreal, Quebec H4R 2E9
Canada

Technical Service

1-800-361-1808
CSD_Techsupport@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Canada:1 (800) 424-9300

2. Hazard(s) identification

Classification

Skin sensitization	Category 1
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Label elements

Warning

Hazard statements

May cause an allergic skin reaction

**Precautionary Statements - Prevention**

Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing should not be allowed out of the workplace
Wear protective gloves/protective clothing/eye protection/face protection

Skin

IF ON SKIN: Wash with plenty of water and soap
If skin irritation or rash occurs: Get medical advice/attention
Take off 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 information

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

3. Composition/information on ingredients**Substance**

Not applicable.

Mixture

The product contains no substances which at their given concentration, are considered to be hazardous to health

Component	Description
Positive Control	BioPlex 2200 APLS IgM Positive Control – Four (4), 1.5 mL vials. The positive controls are provided in a human serum matrix made from defibrinated plasma with added IgM antibody to Cardiolipin (CL) and Beta-2 Glycoprotein I (β2GPI) derived from human disease state plasma. All Controls contain preservatives including ≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate. The controls also contain Amikacin (0.003%), Cycloheximide (C15H23NO4) (0.009%), Amphotericin B (0.002%), Cefotaxime Sodium (0.002%), and Ciprofloxacin (0.005%)
Negative Control	BioPlex 2200 APLS IgM 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 ≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate. The controls also contain Amikacin (0.003%), Cycloheximide (C15H23NO4) (0.009%), Amphotericin B (0.002%), Cefotaxime Sodium (0.002%), and Ciprofloxacin (0.005%)

Chemical name	CAS No.	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Sodium azide	26628-22-8	0.01 - 0.099	-	
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	55965-84-9	0.001 - 0.01	-	

2-methyl-3(2H)-isothiazolone				
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4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
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 physician.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician. Wash skin with soap and water.
Ingestion	Call a physician. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

Symptoms	Itching. Rashes. Hives.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	May cause sensitization in susceptible persons. Treat symptomatically. Contains human source material and / or potentially infectious components.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.
Specific hazards arising from the chemical	Product is or contains a sensitizer. May cause sensitization by skin contact.
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

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.
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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.

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 before reuse.

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.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	Alberta	British Columbia	Ontario	Quebec
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm STEL: 0.3 mg/m ³	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm	CEV: 0.29 mg/m ³ CEV: 0.11 ppm	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm

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).

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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	aqueous solution
Color	amber
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	6-8	
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No 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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Relative vapor density	No data available	None known
Relative density	1	None known
Water solubility	Miscible in water	
Solubility in other solvents	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	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	Not applicable.	
Oxidizing properties	Not applicable.	
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC content	Not applicable	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
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	None known based on information supplied.
Incompatible materials	Metals.
Hazardous decomposition products	None known based on information supplied.

11. 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	May cause sensitization 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

No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium azide 26628-22-8	= 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 55965-84-9	= 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	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 sensitization	May cause sensitization by skin contact.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
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.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium azide 26628-22-8	-	LC50: =0.8mg/L (96h, Oncorhynchus mykiss) LC50: =0.7mg/L (96h,	-	-

		Lepomis macrochirus) LC50: =5.46mg/L (96h, Pimephales promelas)		
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Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.7

Other adverse effects No information available.

13. Disposal considerations

Disposal methods

Waste from residues/unused products Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

TDG Not regulated

DOT Not regulated

MEX Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

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

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

International Inventories

Contact supplier for inventory compliance status

16. Other information

NFPA	Health hazards 2	Flammability 0	Instability 0	Physical and chemical properties -
HMIS	Health hazards 2	Flammability 0	Physical hazards 0	Personal protection X

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

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))
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
Australia 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)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

Prepared By Bio-Rad Laboratories, Environmental Health and Safety.

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Revision Note Reviewed existing information and made minor updates.

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