

# SAFETY DATA SHEET



Revision date 11-Jul-2024

Revision Number 5.3

## 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

### 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  
14620 NE N Woodinville Way  
Woodinville, WA 98072  
USA

**Technical Service** 1-800-224-6723  
TechSupport.USSD@bio-rad.com

### Emergency telephone number

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

## 2. Hazard(s) identification

### Classification

Skin sensitization	Category 1
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### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### Hazard statements

May cause an allergic skin reaction



**Appearance** aqueous solution      **Physical state** Liquid      **Odor** No information available

**Precautionary Statements - Prevention**

Wear protective gloves/clothing and eye/face protection  
Avoid release to the environment

**Precautionary Statements - Response**

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

**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.  
Contains human source material and / or potentially infectious components

### 3. Composition/information on ingredients

**Substance**

Not applicable.

**Mixture**

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-%	Trade secret
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	55965-84-9	0.001 - 0.01	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. First-aid measures

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Contains human source material and / or potentially infectious components. Call a physician. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

<b>Skin contact</b>	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Contains human source material and / or potentially infectious components. Call a physician.

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

<b>Symptoms</b>	Itching. Rashes. Hives.
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	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

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Specific hazards arising from the chemical</b>	Product is or contains a sensitizer. May cause sensitization by skin contact.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	None.
<b>Special protective equipment and precautions for fire-fighters</b>	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**

<b>Personal precautions</b>	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**

<b>Methods for containment</b>	Do not allow into any sewer, on the ground or into any body of water.
<b>Methods for cleaning up</b>	Use: Disinfectant. Clean contaminated surface thoroughly.

## 7. Handling and storage

**Precautions for safe handling**

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with
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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 according to product and label instructions.

## **8. Exposure controls/personal protection**

#### **Control parameters**

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

#### **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**

<b>Physical state</b>	Liquid
<b>Appearance</b>	aqueous solution
<b>Color</b>	amber
<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>
<b>pH</b>	6-8	
<b>Melting point / freezing point</b>	No data available	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flash point</b>	No data available	None known
<b>Evaporation rate</b>	No data available	None known
<b>Flammability</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>Vapor pressure</b>	No data available	None known
<b>Relative vapor density</b>	No data available	None known
<b>Relative density</b>	1	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>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</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>Other information</b>		
<b>Explosive properties</b>	No information available	
<b>Oxidizing properties</b>	No information available	
<b>Softening point</b>	No information available	
<b>Molecular weight</b>	No information available	
<b>VOC content</b>	No information available	
<b>Liquid Density</b>	No information available	
<b>Bulk density</b>	No information available	

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	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.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	Metals.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	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).
<b>Ingestion</b>	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**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
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** No information available.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitization** May cause an allergic skin reaction.

**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.

**Interactive effects** No information available.

## 12. Ecological information

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

**Persistence and degradability** No information available.

**Bioaccumulation****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** 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.

**14. Transport information**

**DOT** Not regulated

**TDG** Not regulated

**MEX** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**15. Regulatory information**

**International Inventories** Contact supplier for inventory compliance status

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive

Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### US State Regulations

#### California Proposition 65

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Cycloheximide - 66-81-9	Developmental
D-Streptamine, O-3-amino-3-deoxy-.alpha.-D-glucopyranosyl-(1->6)-O-[6-amino-6-deoxy-.alpha.-D-glucopyranosyl-(1->4)]-N1-[(2S)-4-amino-2-hydroxy-1-oxobutyl]-2-deoxy- - 37517-28-5	Developmental

### U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sodium azide 26628-22-8	X	X	X
Cycloheximide 66-81-9	X	X	X

### U.S. EPA Label Information

**EPA Pesticide Registration Number** Not applicable

## 16. Other information

<b>NFPA</b>	<b>Health hazards</b> 2	<b>Flammability</b> 0	<b>Instability</b> 0	<b>Special hazards</b> -
<b>HMIS</b>	<b>Health hazards</b> 2	<b>Flammability</b> 0	<b>Physical hazards</b> 0	<b>Personal protection</b> 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)  
 National Institute of Technology and Evaluation (NITE)  
 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  
World Health Organization

**Revision date** 11-Jul-2024

**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**