



# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 11-Jul-2024

Revision Number 4.4

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

### 1.1. Product identifier

**Product Name** BioPlex 2200 APLS IgA Calibrator Set

**Catalogue Number(s)** 6632100

**Nanoforms** Not applicable

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

#### **Legal Entity / Contact Address**

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  
South Africa

EU Representative:  
Bio-Rad  
3 bld Raymond Poincaré  
92430 Marnes-la-Coquette  
France  
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: cdg\_techsupport\_eemea@bio-rad.com

### 1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Ireland: 353-19014670  
 CHEMTREC India: 000-800-100-7141  
 CHEMTREC South Africa: 0-800-983-611

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

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

<b>Skin sensitisation</b>	Category 1 - (H317)
<b>Chronic aquatic toxicity</b>	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 - EU (§28, 1272/2008)

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

P273 - Avoid release to the environment

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

Contains human source material and / or potentially infectious components

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

Component	Description
CAL	APLS IgA Calibrator Set: Three (3) 0.5 mL calibrator vials: One (1) for anti-Cardiolipin (aCL) IgA, one (1) for anti-Beta 2 Glycoprotein I (aβ2GPI) IgA and one (1) vial at zero level for both aCL IgA and aβ2GPI IgA. All Calibrators are in a human serum matrix made from defibrinated plasma with added known analyte concentrations derived from human disease state plasma and contain preservatives including ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives

Chemical name	Weight-%	REACH registration	EC No (EU)	Classification according	Specific	M-Factor	M-Factor
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		number	Index No)	to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)		(long-term)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.001 - 0.01	Not available	(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**

#### Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	53	87.12	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration ≥0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. 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 doctor. 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 doctor.
<b>Ingestion</b>	Contains human source material and / or potentially infectious components. Call a doctor.

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

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

<b>Note to doctors</b>	May cause sensitisation in susceptible persons. Treat symptomatically. 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** 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.

**For emergency responders** Use personal protection recommended in Section 8.

### 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** Do not allow into any sewer, on the ground or into any body of water.

**Methods for cleaning up** Use: Disinfectant. Clean contaminated surface thoroughly.

**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

**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.

**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	European Union	Austria	Belgium	Bulgaria	Croatia
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	-	TWA: 0.05 mg/m³ Sh+	-	-	-
Chemical name	Sweden	Switzerland	United Kingdom		
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	-	S+ TWA: 0.2 mg/m³ STEL: 0.4 mg/m³	-		

**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)****8.2. Exposure controls****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.

**Environmental exposure controls**

No information available.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

Physical state	Liquid
Appearance	aqueous solution
Colour	amber
Odour	No information available.
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	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	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	1	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

**9.2. Other information****9.2.1. Information with regards to physical hazard classes**

Not applicable

**9.2.2. Other safety characteristics**

No information available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

Reactivity	No information available.
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**10.2. Chemical stability**

Stability	Stable under normal conditions.
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**Explosion data**

Sensitivity to mechanical impact None.

Sensitivity to static discharge 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
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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. Information on hazard classes as defined in Regulation (EC) No 1272/2008

##### 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 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).
<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

No information available

##### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitisation</b>	May cause an allergic skin reaction.
<b>Germ cell mutagenicity</b>	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.

#### **11.2. Information on other hazards**

##### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** Not applicable.

##### **11.2.2. Other information**

**Other adverse effects** No information available.

### **SECTION 12: Ecological information**

#### **12.1. Toxicity**

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

**Unknown aquatic toxicity** Contains 0 % of components with unknown hazards to the aquatic environment.

#### **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
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**

Endocrine disrupting properties Not applicable.

**12.7. Other adverse effects**

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 user  
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 user  
Special Provisions None  
14.7 Maritime transport in bulk according to IMO instruments No information available

**RID**

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 user  
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 user  
Special Provisions None

## SECTION 15: Regulatory information

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

#### National regulations

##### Germany

**Water hazard class (WGK)** obviously hazardous to water (WGK 2)

##### European Union

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.

#### Authorisations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	Use restricted. See entry 75.	-

#### Persistent Organic Pollutants

Not applicable

#### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

#### Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	Product-type 2: Disinfectants and algicides not intended for direct application to humans or animals Product-type 4: Food and feed area Product-type 6: Preservatives for products during storage Product-type 11: Preservatives for liquid-cooling and processing systems Product-type 12: Slimeicides Product-type 13: Working or cutting fluid preservatives

#### 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

H301 - Corrosive to the respiratory tract

H301 - Toxic if swallowed

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

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)  
 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  
 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 Note** Reformatted and updated existing information.

**Revision date** 11-Jul-2024

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

**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**