



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 IgA Calibrator Set

Catalogue Number(s) 6632100

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

Supplier

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
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For further information, please contact

Technical Service

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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

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.

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 (a β 2GPI) IgA and one (1) vial at zero level for both aCL IgA and a β 2GPI 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 ($\leq 0.3\%$), sodium benzoate ($\leq 0.1\%$) and sodium azide ($< 0.1\%$) as preservatives

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
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Sodium azide 26628-22-8	0.01 - 0.099	247-852-1 (011-004-00-7)	-	amended) 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)-isothiazolone 55965-84-9	0.001 - 0.01	(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 $\geq 0.1\%$ (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	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.
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	Contains human source material and / or potentially infectious components. Call a doctor.

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

Symptoms	Itching. Rashes. Hives.
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4.3. 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.
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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	United Kingdom
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ 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 controls No 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.

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.

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		
pH (as aqueous solution)	No data available	None known
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

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

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 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 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**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
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)-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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitisation	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.

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.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
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

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
Sodium azide	The substance is not PBT / vPvB
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

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

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)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	PT02 - Disinfectants and algacides not intended for direct 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

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]	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 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