



SAFETY DATA SHEET

This safety data sheet complies with the requirements of:
SS586: 2008 (2014)

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 Calibrator Set

Other means of identification

Catalogue Number(s) 6632100

Pure substance/mixture Mixture

Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone

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 the supplier of the safety data sheet

Corporate Headquarters

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

For further information, please contact

Manufacturer

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

Legal Entity / Contact Address

Bio-Rad Laboratories (Singapore) PTE LTD
3A International Business Park #11-10/16
ICON@IBP
Singapore 609935

Technical Service 6424 0262
ctssingapore@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Singapore: 65-31581349

SECTION 2: Hazards identification

GHS Classification

Skin sensitisation	Category 1
---------------------------	------------

Label elements

**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

Precautionary Statements - Response

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

Take off all contaminated clothing and wash it before reuse

IF ON SKIN: Wash with plenty of water and soap

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other hazards which do not result in classification**SECTION 3: Composition/information on ingredients****Substance**

Not applicable

Mixture

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	EC No (EU Index No)	CAS No.	Weight-%
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	(613-167-00-5)	55965-84-9	0.001 - 0.01

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.

Inhalation

Remove to fresh air.

Eye contact

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 Call a doctor.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

For emergency responders

Self-protection of the first aider No information available.

Indication of any immediate medical attention and special treatment needed

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

SECTION 5: Firefighting measures

Suitable Extinguishing Media

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

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 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

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.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Clean contaminated surface thoroughly.

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

Reference to other sections See section 8 for more information. See section 13 for more information.

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 Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

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

SECTION 8: Exposure controls/personal protection

Control parameters

Occupational 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 protection Wear 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.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

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>
pH		
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	
Vapour pressure	No data available	None known
Relative vapour density	No data available	None known
Relative density	No data available	None known
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	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>	No information available	

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 None under normal processing.

Conditions to avoid

Conditions to avoid None known based on information supplied.

Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 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 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**

No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium benzoate	= 4070 mg/kg (Rat)		
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	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 an allergic skin reaction.
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	Classification not possible.

SECTION 12: Ecological information

Ecotoxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

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

Persistence and degradability

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation There is no data for this product.

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

Mobility

Mobility in soil No information available.

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

Other adverse effects

Other adverse effects No information available

SECTION 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.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

ADR Not regulated

IMDG Not regulated
Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

IATA Not regulated

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture**Singapore****Environmental Public Health Act**

Dispose of waste product or used containers according to local regulations.

Hazardous Waste (Control of Export, Import and Transit) Act

It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Take note that wastes may be subject to export, import, or transit controls pursuant to the Basel convention and/or local regulations implementing the Basel convention.

Poison

None Listed

Workplace Safety and Health Act

Comply with the health and safety at work laws.

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

SECTION 16: Other 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

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) (AELG(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
 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

Label elements

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

Issuing Date Bio-Rad Laboratories, Environmental Health and Safety

Revision date 11-Jul-2024

Revision Note Reformatted and updated existing information.

This safety data sheet complies with the requirements of: SS586: 2008 (2014)

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