

SAFETY DATA SHEET

This safety data sheet complies with the requirements of: \$\$586: 2008 (2014)

Singapore 609935

Revision date 06-Jun-2023 Revision Number 1

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

Product identifier

Product Name BioPlex 2200 HIV Ag-Ab (OUS) Calibrator Set

Other means of identification

Catalogue Number(s) 6633400

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 Manufacturer Legal Entity / Contact Address

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories

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Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Singapore: 65-31581349

SECTION 2: Hazards identification

GHS Classification

Skin sensitisation Category 1A

Label elements

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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 1	HIV Antigen Calibrator – CAL1Three (3) vials with 0.8 mL of antigen calibrator containing purified HIV-		
	p24 antigen (from viral lysate inactivated with a chaotropic agent) in Tris Buffer, protein stabilizer (bovine)		
	andProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservative		
CAL 2	HIV 1/HIV 2 Antibody Calibrator – CAL2Three (3) vials with 0.8 mL of antibody calibrator containing		
	human antibodies to HIV 1 Group M and HIV 2, and purified rabbit antibody to HIV 1 Group O in Tris		
	buffer, protein stabilizer (bovine) and ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide		
	(< 0.1%) as preser¬vative. Human plasma used in preparing this calibrator has been inactivated		

Chemical name	EC No (EU Index No)	CAS No	Weight-%
Sodium chloride	231-598-3	7647-14-5	0.3 - 0.99
Sodium benzoate	208-534-8	532-32-1	0.01 - 0.099
Sodium azide	(011-004-00-7) 247-852-1	26628-22-8	0.01 - 0.099
5-Chloro-2-methyl-3(2H)-isothia zolone, mixture with 2-methyl-3(2H)-isothiazolone	(613-167-00-5)	55965-84-9	0.001 - 0.01

Non-hazardous Proprietary Balance ingredients

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 aiderNo information available.

Indication of any immediate medical attention and special treatment needed

Note to doctorsMay cause sensitisation in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting measures

Suitable Extinguishing Media

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 upClean 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

Chemical name	Singapore	ACGIH TLV
Sodium benzoate		TWA: 2.5 mg/m³ benzoate inhalable
532-32-1		particulate matter
		S*
Sodium azide	STEL: 0.29 mg/m ³	Ceiling: 0.29 mg/m³ Sodium azide
26628-22-8	STEL: 0.11 ppm	Ceiling: 0.11 ppm Hydrazoic acid vapor

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 protectionWear 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

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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 7-8

Melting point / freezing point No data available None known No data available Boiling point / boiling range None known Flash point No data available None known **Evaporation rate** No data available None known None known Flammability (solid, gas) No data available Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone 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
Pecomposition temperature

None known
None known
None known
None known
None known

Kinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Other information 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

Component Information

Somponone information			
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	= 5900 mg/kg(Rat)	> 5000 mg/kg (Rat)	
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)-isothia zolone, 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/irritationBased 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 exposureBased 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.

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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

Chemical name	Algae/aquatic plants	Fish	Crustacea
Sodium chloride	-	LC50: 5560 - 6080mg/L (96h,	EC50: =1000mg/L (48h,
		Lepomis macrochirus)	Daphnia magna)
		LC50: =12946mg/L (96h,	EC50: 340.7 - 469.2mg/L (48h,
		Lepomis macrochirus)	Daphnia magna)
		LC50: 6020 - 7070mg/L (96h,	
		Pimephales promelas)	
		LC50: =7050mg/L (96h,	
		Pimephales promelas)	
		LC50: 6420 - 6700mg/L (96h,	
		Pimephales promelas)	
		LC50: 4747 - 7824mg/L (96h,	
		Oncorhynchus mykiss)	
Sodium benzoate	-	LC50: 420 - 558mg/L (96h,	EC50: <650mg/L (48h, Daphnia
		Pimephales promelas)	magna)
		LC50: >100mg/L (96h,	
		Pimephales promelas)	
Sodium azide	-	LC50: =0.8mg/L (96h,	-
		Oncorhynchus mykiss)	
		LC50: =0.7mg/L (96h, Lepomis	
		macrochirus)	
		LC50: =5.46mg/L (96h,	
		Pimephales promelas)	

Persistence and degradability

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation There is no data for this product.

Chemical name	Partition coefficient
Sodium benzoate	-2.13
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	0.7
2-methyl-3(2H)-isothiazolone	

Mobility

Mobility in soil No information available.

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium chloride	The substance is not PBT / vPvB
Sodium benzoate	The substance is not PBT / vPvB
Sodium azide	The substance is not PBT / vPvB
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	The substance is not PBT / vPvB
2-methyl-3(2H)-isothiazolone	

Other adverse effects

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Other adverse effects No information available

SECTION 13: Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of waste in accordance with environmental legislation. Dispose of in accordance

with local regulations.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IMDG Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulated

SECTION 15: Regulatory information

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

<u>Singapore</u>

Environmental Protection and Management (Hazardous Substances) Regulations

Verify that licence requirements are met.

	Chemical name	Hazardous Substances	transport
Γ	Sodium azide	Exclusions: Air bag devices in motor	0kg
		vehicles	

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

See section 8 for national exposure control parameters. 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 * 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) EPA (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

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)

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

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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