



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
GB/T 16483-2008, GB/T 17519-2013

Product Name BioPlex 2200 Syphilis Total & RPR Calibrator Set

Revision date 12-Jan-2023

Revision Number 2

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

Product identifier

Product Name BioPlex 2200 Syphilis Total & RPR Calibrator Set

Catalogue Number(s) 12000651

Other means of identification

Pure substance/mixture Mixture

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
6565-185th Ave NE
Redmond, WA 98052
USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd.
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239/2, Rajdamri Road, Lumpini,
Pathumwan, Bangkok 10330
Thailand

Technical Service +66 2 652 8313
ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic
Restricted to professional users
Use according to package label instructions

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance Liquid **Physical state** No information available **Odour** No data available

Classification of the substance or mixture

Skin sensitisation	Category 1A
Hazardous to the Aquatic Environment - Acute Hazard	Category 3
Hazardous to the Aquatic Environment - Chronic Hazard	Category 3

Label elements



Signal word

Warning

Hazard statements

May cause an allergic skin reaction
Harmful to aquatic life with long lasting effects

Prevention

Avoid breathing dust/fume/gas/mist/vapours/spray
Contaminated work clothing should not be allowed out of the workplace
Wear protective gloves/protective clothing/eye protection/face protection
Avoid release to the environment

Response

Specific treatment (see .? on this label)
IF ON SKIN: Wash with plenty of water and soap
If skin irritation or rash occurs: Get medical advice/attention
Take off all contaminated clothing and wash it before reuse

Disposal

Dispose of contents/container to an approved waste disposal plant

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.
Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

Contains human source material and / or potentially infectious components.

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Component	Description
Calibrator	Syphilis Total & RPR Calibrators: 5 x 0.5 mL vials. The calibrators are provided in a human serum matrix made from defibrinated plasma with added known analyte concentrations of Treponema pallidum and/ or reagin antibodies derived from human disease state plasma, and added preservatives including $\leq 0.3\%$ ProClin 300, $< 0.1\%$ sodium azide and $\leq 0.1\%$ sodium benzoate

SECTION 4: First aid measures

Description of necessary first aid measures

General advice	No hazards which require special first aid measures.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash skin with soap and water.
Ingestion	Rinse mouth thoroughly with water.
<u>Most important symptoms and effects, both acute and delayed</u>	No information available.
<u>For emergency responders</u>	No information available.
<u>Note to doctors</u>	Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.
<u>Specific hazards arising from the chemical</u>	No information available.
<u>Special protective actions for fire-fighters</u>	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	See section 8 for more information.
For emergency responders	Use personal protection recommended in Section 8.
<u>Environmental precautions</u>	See Section 12 for additional Ecological Information.
<u>Methods and material for containment and cleaning up</u>	Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly labelled containers.
<u>Precautions to prevent secondary hazards</u>	Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

<u>Precautions for safe handling</u>	Handle in accordance with good industrial hygiene and safety practice. See Section 8 for information on appropriate personal protective equipment.
<u>Conditions for safe storage, including any incompatibilities</u>	Keep containers tightly closed in a dry, cool and well-ventilated place.
<u>Incompatible materials</u>	None known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

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.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Liquid
Colour	amber
Physical state	No information available
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
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	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
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	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Additional information		
Explosive properties	Not applicable	
Oxidising properties	Not applicable	

SECTION 10: Stability and reactivity

Stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

0.005 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
0.005 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
0.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
0.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour)
0.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

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	Based on available data, the classification criteria are not met.
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.
Specific target organ toxicity — single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity — repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

<u>Ecotoxicity</u>	The environmental impact of this product has not been fully investigated.
<u>Unknown aquatic toxicity</u>	0.005 % of the mixture consists of component(s) of unknown hazards to the aquatic environment
<u>Persistence and degradability</u>	No information available.
<u>Bioaccumulative potential</u>	There is no data for this product.
<u>Mobility in soil</u>	No information available.

SECTION 13: Disposal considerations

<u>Waste chemicals</u>	Dispose of waste in accordance with environmental legislation. Dispose of in accordance with local regulations.
<u>Contaminated packaging</u>	Do not reuse empty containers.

SECTION 14: Transport information

<u>IMDG</u>	Not regulated
Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available
<u>IATA</u>	Not regulated
<u>China</u>	Not regulated
Special precautions for user Please refer to the applicable dangerous goods regulations for additional information	

SECTION 15: Regulatory information

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

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors: Not applicable.
Catalogue of occupational diseases: Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances Contact supplier for inventory compliance status.

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

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

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Revision Note Significant changes throughout SDS. Review all sections.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
C	Carcinogen		

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) (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)
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

Disclaimer

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End of Safety Data Sheet