

SAFETY DATA SHEET



Revision date 11-Jul-2024

Revision Number 4.1

1. Identification

Product identifier

Product Name BioPlex 2200 Lyme Total Control Set

Other means of identification

Catalog Number(s) 12000879

Recommended use of the chemical and restrictions on use

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

Details of the supplier of the safety data sheet

Corporate Headquarters

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

Manufacturer Address

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

Legal Entity / Contact Address

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

Technical Service 1-800-224-6723
TechSupport.USSD@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

Skin sensitization	Category 1A
--------------------	-------------

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

May cause an allergic skin reaction



Appearance aqueous solution **Physical state** Liquid **Odor** No information available

Precautionary Statements - Prevention

Wear protective gloves/clothing and eye/face protection
Avoid release to the environment

Precautionary Statements - Response

IF ON SKIN: Wash with plenty of water and soap
If skin irritation or rash occurs: Get medical advice/attention

Precautionary Statements - Disposal

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Other information

Harmful to aquatic life with long lasting effects.
Contains human source material and / or potentially infectious components

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Component	Description
Positive Control	BioPlex 2200 Lyme Total Positive Control - four (4) 1.5 mL vials. The positive control vials that are provided in a human serum matrix made from defibrinated/delipidated plasma, with known analyte concentrations of <i>Borrelia burgdorferi</i> antibodies. All controls contain preservatives including $\leq 0.3\%$ ProClin 300, $< 0.1\%$ sodium azide and $\leq 0.1\%$ sodium benzoate
Negative Control	BioPlex 2200 Lyme Total Negative Control - Two (2) 1.5 mL vials. The negative controls are provided in a human serum matrix made from defibrinated/delipidated plasma. All controls contain preservatives including $\leq 0.3\%$ ProClin 300, $< 0.1\%$ sodium azide and $\leq 0.1\%$ sodium benzoate

Chemical name	CAS No.	Weight-%	Trade secret
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	55965-84-9	0.001 - 0.01	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

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	Contains human source material and / or potentially infectious components. Call a physician. 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 physician.

Ingestion Contains human source material and / or potentially infectious components. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically. Contains human source material and / or potentially infectious components.

5. Fire-fighting measures

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical Product is or contains a sensitizer. May cause sensitization by skin contact.

Explosion data
Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

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.

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.

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 before reuse.

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.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

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).

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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid
Appearance aqueous solution
Color amber
Odor No information available
Odor 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	No data available	

limits		
Vapor pressure	No data available	None known
Relative vapor density	No data available	None known
Relative density	1	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

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
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.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Metals.
Hazardous decomposition products	None known based on information supplied.

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 sensitization 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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	= 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 sensitization	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.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Persistence and degradability No information available.

Bioaccumulation

Component Information

Chemical name	Partition coefficient
---------------	-----------------------

5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.7
---	-----

Other adverse effects No information available.

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. Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT Not regulated

TDG Not regulated

MEX Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

International Inventories Contact supplier for inventory compliance status

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sodium azide 26628-22-8	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	Health hazards 2	Flammability 0	Instability 0	Special hazards -
HMIS	Health hazards 2	Flammability 0	Physical hazards 0	Personal protection X

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) (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)
 Australia 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)
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program
 Organization for Economic Co-operation and Development Screening Information Data Set
 World Health Organization

Revision date 11-Jul-2024

Revision Note Reviewed existing information and made minor updates.

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