SAFETY DATA SHEET



Revision date 11-Jul-2024 Revision Number 3.1

1. Identification

Product identifier

Product Name BioPlex 2200 ANA Screen Control Set

Other means of identification

Catalog Number(s) 6631131

Recommended use of the chemical and restrictions on use

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

users

Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturer AddressBio-Rad Laboratories Inc.Bio-Rad Laboratories1000 Alfred Nobel Drive14620 NE N Woodinville WayHercules, CA 94547Woodinville, WA 98072

USA

nufacturer Address
Rad Laboratories

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

USA

Skin sensitization Category 1A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

May cause an allergic skin reaction



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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.

<u>Mixture</u>

Component	Description
	BioPlex 2200 ANA Screen Positive Controls: Four (4) 1.5 mL vials. The positive controls are provided in a human serum matrix made from defibrinated plasma with added known analyte concentrations derived from human disease state plasma. All reagents contain preservatives including≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate
	BioPlex 2200 ANA Screen Negative Controls: Two (2) 1.5 mL vials. The negative controls are provided in a human serum matrix made from defibrinated plasma. All reagents contain preservatives including≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate

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

^{*}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 Call a physician. Rinse immediately with plenty of water, also under the eyelids, for at least

15 minutes. Contains human source material and / or potentially infectious components.

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.

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

components.

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

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 Clean contaminated surface thoroughly. Use:. Disinfectant.

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.

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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 LimitsThe 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 protectionWear 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 6-8Melting point / freezing point No data available None known

Initial boiling point and boiling rangeNo data available
None known
Flash point
No data available
None known
Evaporation rate
No data available
None known
Flammability
No data available
None known
None known
Flammability Limit in Air
None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

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limits

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

Water solubility Miscible in water

Solubility(ies) No data available None known No data available **Partition coefficient** None known None known **Autoignition temperature** No data available None known No data available **Decomposition temperature** No data available None known Kinematic viscosity 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.

Avoid contact with metals. This product contains sodium azide. Sodium azide can react with Possibility of hazardous reactions

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 None known based on information supplied.

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.

Eve contact Specific test data for the substance or mixture is not available.

May cause sensitization by skin contact. Specific test data for the substance or mixture is Skin contact

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

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Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
5-Chloro-2-methyl-3(2H)-isothia	= 53 mg/kg (Rat)	= 87.12 mg/kg (Rabbit)	-
zolone, mixture with			
2-methyl-3(2H)-isothiazolone			
55965-84-9			

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritationNo 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.

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		

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

Other adverse effects No information available.

13. Disposal considerations

Disposal methods

Waste from residues/unused

products

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.

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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	X	X	X
26628-22-8			

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

10. Othici illioilliation	16.	Other	informatio	n
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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 Significant changes throughout SDS. Review all sections.

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

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