SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
UK REACH Regulations (SI 2019/758 as amended)

Revision date 12-Jan-2023 **Revision Number** 2

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

1.1. Product identifier

Product Name BioPlex 2200 ANA Screen Calibrator set

Catalogue Number(s) 6631101

Pure substance/mixture Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against No information available

1.3. 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
The Junction
Station Road
Watford, WD17 1ET
UK

Bio-Rad Laboratories Pvt. Ltd.
Bio-Rad House
86-87, Udyog Vihar Phase IV Gurgaon
122005
Haryana India

Bio-Rad Laboratories (Pty) Ltd.
34 Bolton Road
Parkwood, Johannesburg 2193
South Africa

For further information, please contact

Technical Service 00800 00246 723
Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Chronic aquatic toxicity	Category 3 - (H412)

2.2. Label elements

Hazard statements
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements
P501 - Dispose of contents/ container to an approved waste disposal plant
P280 - Wear protective gloves/protective clothing/eye protection/face protection

2.3. Other hazards

Contains components derived from human urine. Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Component	Description
Calibrator	ANA Screen calibrators: 7 x 0.5 mL vials. The calibrators are provided in a human serum matrix made from defibrinated plasma with added known analyte concentrations derived from human disease state plasma. All Calibrators contain preservatives including ≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium azide 26628-22-8	0.01 - 0.099	247-852-1	-	(EUH032) Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.001 - 0.01	-	-	(EUH071) Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1C (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-	100	100

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >= 0.1% (UK REACH Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Remove to fresh air.

Eye contact Contains human source material and / or potentially infectious components.

Skin contact In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and water.

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

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors Contains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

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

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. 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.

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

6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Follow universal and standard precautions for handling potentially infectious materials.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	United Kingdom
Sodium azide 26628-22-8	TWA: 0.1 mg/m^3 STEL: 0.3 mg/m^3 Sk*

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

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering controls No information available.

Personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	aqueous solution
Colour	amber
Odour	No information available.
Odour threshold	No information available

Property	**Values**	**Remarks • Method**
Melting point / freezing point	No data available	None known
Boiling point / boiling range	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	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	6-8	
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

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.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

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

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity
No information available

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
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 No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

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.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium azide	-	LC50: =0.8mg/L (96h, Oncorhynchus mykiss) LC50: =0.7mg/L (96h, Lepomis macrochirus) LC50: =5.46mg/L (96h, Pimephales promelas)	-	-

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

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

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

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

12.6. Endocrine disrupting properties

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment 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.

SECTION 14: Transport information

IATA

14.1 UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6 Special Precautions for Users
Special Provisions None

IMDG

14.1 UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6 Special Precautions for Users
Special Provisions None
14.7 Maritime transport in bulk according to IMO instruments No information available

RID

14.1 UN number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6 Special Precautions for Users
Special Provisions None

ADR

14.1 UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6 Special Precautions for Users
Special Provisions None

SECTION 15: Regulatory information

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

National regulations

Authorisations and/or restrictions on use:
This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants
Not applicable

Export Notification requirements
Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)
Not applicable

The Ozone-Depleting Substances Regulations 2015
Not applicable

The Biocidal Products Regulations 2001 (as amended)

Chemical name	The Biocidal Products Regulations 2001 (as amended)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals PT06 - Preservatives for products during storage PT13 - Working or cutting fluid preservatives PT04 - Food and feed area PT11 - Preservatives for liquid-cooling and processing systems PT12 - Slimicides

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)
Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)
Not applicable

International Inventories Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3
EUH032 - Contact with acids liberates very toxic gas
EUH071 - Corrosive to the respiratory tract
H300 - Fatal if swallowed
H301 - Toxic if swallowed
H310 - Fatal in contact with skin
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage
H330 - Fatal if inhaled
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Legend
SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
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)
National Institute of Technology and Evaluation (NITE)
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
World Health Organization

Revision date 12-Jan-2023

Revision Note Significant changes throughout SDS. Review all sections
This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended)
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

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