

# SAFETY DATA SHEET

**Legal Entity / Contact Address** 

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Bio-Rad Laboratories Ltd.

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

Product Name BioPlex 2200 Celiac IgG 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 Celiac IgG Calibrator Set

Catalogue Number(s) 6632200

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

**Corporate Headquarters** Manufacturer Bio-Rad Laboratories Inc. **Bio-Rad Laboratories** 1000 Alfred Nobel Drive 6565-185th Ave NE

Hercules, CA 94547 Redmond, WA 98052

USA USA

**Technical Service** +66 2 652 8313

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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

Physical state Liquid Odour No data available Appearance aqueous solution

#### 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

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#### Signal word

Warning

#### **Hazard statements**

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

#### **Precautionary statements**

#### 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
CAL	BioPlex 2200 Celiac IgG: Nine (9) 0.5 mL vials for anti-tissue Transglutaminase (tTG) and
	anti-deamidated gliadin peptide (DGP) IgG.The calibrators contain MOPS (3-[N-Morpholino]
	propanesul¬fonic acid) buffer supplemented with protein stabilizer (porcine and human for Celiac IgG.),
	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

### SECTION 4: First aid measures

#### Description of necessary first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Remove to fresh air. Inhalation

**Eve contact** Contains human source material and / or potentially infectious components. Rinse

thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a doctor.

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. Wash skin with soap and water.

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

Most important symptoms and effects, both acute and delayed

Itching. Rashes. Hives.

For emergency responders No information available.

May cause sensitisation in susceptible persons. Treat symptomatically. Contains human Note to doctors

source material and / or potentially infectious components.

## **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.

Specific hazards arising from the

chemical

Product is or contains a sensitiser. May cause sensitisation by skin contact.

Special protective actions 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

Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal Personal precautions

protective equipment as required. Evacuate personnel to safe areas. Keep people away

from and upwind of spill/leak.

Use personal protection recommended in Section 8. For emergency responders

**Environmental precautions** See Section 12 for additional Ecological Information.

Do not allow into any sewer, on the ground or into any body of water. Clean contaminated Methods and material for

surface thoroughly. Use:. Disinfectant. containment and cleaning up

Precautions to prevent secondary

hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

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## SECTION 7: Handling and storage

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with Precautions for safe handling

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. Follow universal and standard precautions for handling potentially infectious materials. See Section 8 for information on appropriate

personal protective equipment.

Conditions for safe storage, including any incompatibilities Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children. Store according to product and label instructions.

Incompatible materials Metals.

### 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.

Showers **Engineering controls** 

> Eyewash stations Ventilation systems.

#### Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields (or goggles). Eye/face protection

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.

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

#### SECTION 9: Physical and chemical properties

### Information on basic physical and chemical properties

aqueous solution **Appearance** 

Colour amber Liquid Physical state

No information available Odour **Odour threshold** No information available

Property	<u>Values</u>	Remarks • Method
рН		
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	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
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	
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## SECTION 10: Stability and reactivity

**Stability** Stable under normal conditions.

<u>Possibility of hazardous reactions</u> 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.

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

<u>Conditions to avoid</u> None known based on information supplied.

Incompatible materials Metals.

<u>Hazardous decomposition products</u> 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

1.005 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

1.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

1.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour)

1.005 % 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 May cause sensitisation by skin contact.

Based on available data, the classification criteria are not met. Germ cell mutagenicity

Carcinogenicity Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met. Reproductive toxicity

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.

Based on available data, the classification criteria are not met. **Aspiration hazard** 

## **SECTION 12: Ecological information**

**Ecotoxicity** Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicity 0.005 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

Bioaccumulative potential There is no data for this product.

Mobility in soil No information available.

### **SECTION 13: Disposal considerations**

Waste chemicals Flush pipes with water frequently if discarding solutions containing Sodium azide into metal

piping systems. Dispose of in accordance with local regulations. Dispose of waste in

accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

### SECTION 14: Transport information

Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulated

China Not regulated

Special precautions for user

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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

12-Jan-2023 Revision date

**Revision Note** Reformatted and updated existing information.

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

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) (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

#### **Disclaimer**

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**End of Safety Data Sheet**