

SAFETY DATA SHEET

Legal Entity / Contact Address

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

Product Name BioPlex 2200 MMV IgM Control 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 MMV IgM Control Set

Catalogue Number(s) 12000931

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**

Bio-Rad Laboratories Ltd. 1000 Alfred Nobel Drive 6565-185th Ave NE 1st and 2nd Floor, Lumpini 1 Building Hercules, CA 94547 Redmond, WA 98052

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Thailand

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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

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	
Positive Control	BioPlex 2200 MMV IgM Positive Control - Two (2) 1.5 mL vials. The positive control is provided in a	
	human serum matrix made from defibrinated plasma with added known analyte concentrations consisting	
	of a HuCAL® recombinant IgM anti¬body for measles, and human disease state plasma derived	
	antibodies for mumps and VZV. All controls contain preservatives including ≤ 0.3% ProClin 300, < 0.1%	
	sodium azide and ≤ 0.1% sodium benzoate	
Negative Control	BioPlex 2200 MMV IgM Negative Control - Two (2) 1.5 mL vials. The negative controls are provided in a	
	human serum matrix made from defibrinated plasma. All controls 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.

Inhalation Remove to fresh air.

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.

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation Skin contact

or allergic reactions see a doctor. Wash skin with soap and water.

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

Most important symptoms and effects, both acute and delayed Itching. Rashes. Hives.

No information available. For emergency responders

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

source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the **Suitable Extinguishing Media**

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

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.

For emergency responders Use personal protection recommended in Section 8.

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for

Do not allow into any sewer, on the ground or into any body of water. Clean contaminated containment and cleaning up

surface thoroughly. Use:. Disinfectant.

Precautions to prevent secondary Clean contaminated objects and areas thoroughly observing environmental regulations.

hazards

SECTION 7: Handling and storage

Precautions for 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 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.

See section 16 for terms and abbreviations Note

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

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

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Physical state Liquid

Odour No information available Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pН

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 No data available **Evaporation rate** 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 pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility

Solubility(ies)

No data available
No data available
No data available

Partition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone 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
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

None known

gases.

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

Conditions to avoid None known based on information supplied.

Incompatible materials Metals.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

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

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.

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

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicity 0 % 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

IMDG Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

Not regulated IATA

Not applicable

<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:

Catalogue of occupational diseases:

Not applicable.

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

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

Revision date 12-Jan-2023

Revision Note Reviewed existing information and made minor updates.

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) (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