

SAFETY DATA SHEET

Legal Entity / Contact Address

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 EBV IgG Calibrator Set

Revision date 23-Feb-2023 **Revision Number** 2.1

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

Product identifier

Product Name BioPlex 2200 EBV IgG Calibrator Set

Catalogue Number(s) 6631200, 6631201

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

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Thailand

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

May cause allergic skin reaction

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

Wear protective gloves/protective clothing/eye protection/face protection

Avoid breathing dust/fume/gas/mist/vapours/spray

Avoid release to the environment

Contaminated work clothing should not be allowed out of the workplace

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 in accordance with local, regional, national, and international regulations as applicable

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Allergic reactions (sensitiser). Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Chronic effects: Not applicable.

Environmental hazards

This material is a water pollutant. Keep out of drains, sewers, ditches and waterways. Minimise use of water to prevent environmental contamination

Other hazards which do not result in classification

Not applicable

Contains human source material and $\ensuremath{/}$ or potentially infectious components.

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Component	Description
CAL	Seven (7) 0.5 mL EBV IgG calibrator vials. The calibrators are provided in a human serum matrix made
	from defibrinated plasma with added known analyte concentrations of EBV NA-1 IgG, EBV VCA IgG, and
	EBV EA-D IgG derived from human disease state plasma, and added preservatives including ProClin
	300 at a concentration of ≤ 0.3% and sodium benzoate (≤ 0.1%)

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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.

Eye 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.

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

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

<u>chemical</u>

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.

Environmental precautionsSee Section 12 for additional Ecological Information.

<u>Methods and material for</u>

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

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 None known based on information supplied.

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

Remarks • Method Property Values 7.4 рH

Melting point / freezing point No data available None known Boiling point / boiling range No data available None known No data available Flash point None known No data available None known **Evaporation rate** None known Flammability (solid, gas) No data available Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

No data available None known Vapour pressure 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

SECTION 10: Stability and reactivity

Stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

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

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.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

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.

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

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.

0.1 % of the mixture consists of component(s) of unknown hazards to the aquatic Unknown aquatic toxicity

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 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

Not regulated IATA

China 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

Review Date 23-Feb-2023

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 SubstancesContact 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

Bio-Rad Laboratories, Environmental Health and Safety **Prepared By**

Revision date 23-Feb-2023

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