



SAFETY DATA SHEET

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

Product Name BioPlex 2200 ToRC IgM 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 ToRC IgM Calibrator Set

Catalogue Number(s) 12000677

Other means of identification

Pure substance/mixture Mixture

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.
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239/2, Rajdamri Road, Lumpini,
Pathumwan, Bangkok 10330
Thailand

Technical Service +66 2 652 8313
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

Appearance aqueous solution **Physical state** Liquid **Odour** No data available

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

**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 |
|------------|---|
| Calibrator | Two (2) 0.5 mL ToRC IgM calibrator vials The calibrators are provided in a human serum matrix made from defibrinated plasma with added known analyte concentrations consisting of HuCAL recombi-nant IgM antibodies for rubella and human disease state plasma derived antibodies for T. gondii and CMV. All calibrators contain ProClin 300 ($\leq 0.3\%$), sodium benzoate ($\leq 0.1\%$) and sodium azide ($< 0.1\%$) as preservatives |

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. |
| <u>Most important symptoms and effects, both acute and delayed</u> | Itching. Rashes. Hives. |
| <u>For emergency responders</u> | No information available. |
| <u>Note to doctors</u> | 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. |
| <u>Specific hazards arising from the chemical</u> | Product is or contains a sensitiser. May cause sensitisation by skin contact. |
| <u>Special protective actions for fire-fighters</u> | 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. |
| <u>Environmental precautions</u> | See Section 12 for additional Ecological Information. |
| <u>Methods and material for containment and cleaning up</u> | Do not allow into any sewer, on the ground or into any body of water. Clean contaminated surface thoroughly. Use: Disinfectant. |
| <u>Precautions to prevent secondary hazards</u> | Clean contaminated objects and areas thoroughly observing environmental regulations. |

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.

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.

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).

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.

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

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

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|--|-------------------|-------------------------|
| pH | | |
| 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 limits | No data available | |
| Lower flammability or explosive limits | No data available | |
| 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 |
| <u>Additional information</u> | | |
| Explosive properties | Not applicable | |
| Oxidising properties | Not applicable | |

SECTION 10: Stability and reactivity

| | |
|---|---|
| <u>Stability</u> | 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. |
| <u>Incompatible materials</u> | Metals. |
| <u>Hazardous decomposition products</u> | 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. |
| 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

| | |
|---|---|
| <u>Ecotoxicity</u> | 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 |
| <u>Persistence and degradability</u> | No information available. |
| <u>Bioaccumulative potential</u> | There is no data for this product. |
| <u>Mobility in soil</u> | No information available. |

SECTION 13: Disposal considerations

| | |
|--------------------------------------|--|
| <u>Waste chemicals</u> | 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. |
| <u>Contaminated packaging</u> | Do not reuse empty containers. |

SECTION 14: Transport information

| | |
|--|--------------------------|
| <u>IMDG</u> | Not regulated |
| Transport in bulk according to Annex II of MARPOL and the IBC Code | No information available |
| <u>IATA</u> | Not regulated |
| <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: | Not applicable. |
| Catalogue of occupational diseases: | Not applicable. |

Regulations on the Control over Safety of Hazardous Chemicals

| | |
|---|-----------------|
| <u>Inventory of hazardous chemicals</u> | Not applicable. |
|---|-----------------|

| | |
|---|----------------|
| <u>GB 18218-2009 Identification of major hazard installations for dangerous chemicals</u> | 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 |
|--------------------|---|

| | |
|----------------------|-------------|
| 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