

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 25-OH Vitamin D Calibrator Set

Revision date 15-Jun-2023

Revision Number 2

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

Product identifier

Product Name BioPlex 2200 25-OH Vitamin D Calibrator Set

Catalogue Number(s) 12006552

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

1st and 2nd Floor, Lumpini 1 Building

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

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd.

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

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

Label elements

Page 1/8 CGHS / EN



Signal word

Warning

Hazard statements

May cause an allergic skin reaction Harmful to aquatic life

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

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

Contains animal source material

Contains human source material and / or potentially infectious components.

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Component	Description	
CAL	BioPlex 2200 25-OH Vitamin D Calibrator Set: Six (6) 0.5 mL 25-OH Vitamin D calibrator vials.Calib	
	level 1 contains 25% horse serum without 25-OH Vitamin D. The calibrator levels2 to 6 are provided in a	
	Vitamin D depleted human serum matrix supplemented with knownconcentration of 25-hydroxyvitamin	
	D3. All calibrators contain ProClin 950 (≤ 0.3%), sodiumbenzoate (≤ 0.1%) and	
	5-Bromo-5-nitro-1,3-dioxane (< 0.1%) as preservatives	

Page 2/8

Product Name BioPlex 2200 25-OH Vitamin D Calibrator

SECTION 4: First aid measures

Description of necessary first aid measures

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

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.

Revision date 15-Jun-2023

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.

No information available. For emergency responders

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.

For emergency responders Use personal protection recommended in Section 8.

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

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.

BioPlex 2200 25-OH Vitamin D Calibrator **Product Name**

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

Revision date 15-Jun-2023

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 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.

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.

Showers **Engineering controls**

> 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

aqueous solution **Appearance**

Colour amber

Product Name BioPlex 2200 25-OH Vitamin D Calibrator

Set

Physical state Liquid

Odour No information available Odour threshold No information available

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

рΗ

No data available Melting point / freezing point 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 pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility

Miscible in water

Salubility

Miscible in water

No data available

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

<u>Stability</u> Stable under normal conditions.

<u>Possibility of hazardous reactions</u> None under normal processing.

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> 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

Revision date 15-Jun-2023

BioPlex 2200 25-OH Vitamin D Calibrator **Product Name**

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.

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.

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

SECTION 12: Ecological information

Harmful to aquatic life. **Ecotoxicity**

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

Dispose of in accordance with local regulations. Dispose of waste in accordance with Waste chemicals

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 Not regulated China

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

Revision date 15-Jun-2023

Product Name BioPlex 2200 25-OH Vitamin D Calibrator

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

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

Revision date 15-Jun-2023

Revision Note Reviewed existing information and made minor updates.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA (time-weighted average) STEL (Short Term Exposure Limit) TWA STEL

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

Revision date 15-Jun-2023

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

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