



# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
UK REACH Regulations (SI 2019/758 as amended)

Revision date 15-Jun-2023

Revision Number 1

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

### 1.1. Product identifier

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

**Catalogue Number(s)** 12006552

**Pure substance/mixture** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended use** In vitro diagnostic Restricted to professional users Use according to package label instructions

**Uses advised against** No information available

### 1.3. 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  
The Junction  
Station Road  
Watford, WD17 1ET  
UK

Bio-Rad Laboratories Pvt. Ltd.  
Bio-Rad House  
86-87, Udyog Vihar Phase IV Gurgaon  
122005  
Haryana India

Bio-Rad Laboratories (Pty) Ltd.  
34 Bolton Road  
Parkwood, Johannesburg 2193  
South Africa

For further information, please contact

**Technical Service** 00800 00246 723  
Techsupport.UK@bio-rad.com

### 1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

### 2.2. Label elements

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)

**Hazard statements**

Not classified Not a hazardous substance or mixture according to the Globally Harmonised System (GHS)  
EUH208 - Contains 3(2H)-Isothiazolone, 2-methyl-. May produce an allergic reaction.

**Precautionary statements**

P280 - Wear protective gloves/protective clothing/eye protection/face protection

**2.3. Other hazards**

Contains animal source material. (Horse). Harmful to aquatic life.

## SECTION 3: Composition/information on ingredients

**3.1 Substances**

Not applicable

**3.2 Mixtures**

| Component | Description  |
|-----------|--|
| CAL       | BioPlex 2200 25-OH Vitamin D Calibrator Set: Six (6) 0.5 mL 25-OH Vitamin D calibrator vials. Calibrator level 1 contains 25% horse serum without 25-OH Vitamin D. The calibrator levels 2 to 6 are provided in a Vitamin D depleted human serum matrix supplemented with known concentration of 25-hydroxyvitamin D3. All calibrators contain ProClin 950 ( $\leq 0.3\%$ ), sodium benzoate ( $\leq 0.1\%$ ) and 5-Bromo-5-nitro-1,3-dioxane ( $< 0.1\%$ ) as preservatives |

| Chemical name                               | Weight-%     | EC No (EU Index No)         | UK REACH registration number | Classification according to GB CLP (SI 2020/1567 as amended)   | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---|--------------|-----------------------------|------------------------------|--|------------------------------------|----------|----------------------|
| 3(2H)-Isothiazolone, 2-methyl-<br>2682-20-4 | 0.01 - 0.099 | (613-326-00-9)<br>220-239-6 | -                            | (EUH071)<br>Acute Tox. 3 (H301)<br>Acute Tox. 3 (H311)<br>Acute Tox. 2 (H330)<br>Skin Corr. 1B (H314)<br>Eye Dam. 1 (H318)<br>Skin Sens. 1A (H317)<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410) | -                                  | 10       | 1                    |

**Full text of H- and EUH-phrases: see section 16**

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (UK REACH Article 59)

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

|              |  |
|--------------|--|
| Inhalation   | Remove to fresh air.   |
| Eye contact  | Contains human source material and / or potentially infectious components. Call a doctor. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. |
| Skin contact | Wash with soap and water.  |
| Ingestion    | Contains human source material and / or potentially infectious components. Call a doctor.  |

#### **4.2. Most important symptoms and effects, both acute and delayed**

|          |                           |
|----------|---------------------------|
| Symptoms | No information available. |
|----------|---------------------------|

#### **4.3. Indication of any immediate medical attention and special treatment needed**

|                 |  |
|-----------------|--|
| Note to doctors | Contains human source material and / or potentially infectious components. |
|-----------------|--|

### **SECTION 5: Firefighting measures**

#### **5.1. Extinguishing media**

|                              |   |
|------------------------------|---|
| Suitable Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
|------------------------------|---|

|            |  |
|------------|--|
| Large Fire | CAUTION: Use of water spray when fighting fire may be inefficient. |
|------------|--|

|                                |   |
|--------------------------------|---|
| Unsuitable extinguishing media | Do not scatter spilled material with high pressure water streams. |
|--------------------------------|---|

#### **5.2. Special hazards arising from the substance or mixture**

|  |                           |
|--|---------------------------|
| Specific hazards arising from the chemical | No information available. |
|--|---------------------------|

#### **5.3. Advice for firefighters**

|  |  |
|--|--|
| Special protective equipment and precautions for fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. |
|--|--|

### **SECTION 6: Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

|                      |                              |
|----------------------|------------------------------|
| Personal precautions | Ensure adequate ventilation. |
|----------------------|------------------------------|

|                          |   |
|--------------------------|---|
| For emergency responders | Use personal protection recommended in Section 8. |
|--------------------------|---|

#### **6.2. Environmental precautions**

|                           |   |
|---------------------------|---|
| Environmental precautions | See Section 12 for additional Ecological Information. |
|---------------------------|---|

#### **6.3. Methods and material for containment and cleaning up**

|                         |   |
|-------------------------|---|
| Methods for containment | Do not allow into any sewer, on the ground or into any body of water. |
|-------------------------|---|

|                         |   |
|-------------------------|---|
| Methods for cleaning up | Use: Disinfectant. Clean contaminated surface thoroughly. |
|-------------------------|---|

|                                 |  |
|---------------------------------|--|
| Prevention of secondary hazards | Clean contaminated objects and areas thoroughly observing environmental regulations. |
|---------------------------------|--|

**6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

**Advice on safe handling** Ensure adequate ventilation.

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

**7.2. Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Store according to product and label instructions.

**7.3. Specific end use(s)**

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Biological occupational exposure limits** This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

**Derived No Effect Level (DNEL)** No information available.

**Predicted No Effect Concentration (PNEC)** No information available.

**8.2. Exposure controls**

**Engineering controls** No information available.

**Personal protective equipment**

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

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**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

### 9.1. Information on basic physical and chemical properties

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

| Property                               | Values                   | Remarks • Method |
|--|--------------------------|------------------|
| Melting point / freezing point         | No data available        | None known       |
| Boiling point / boiling range          | 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        |                  |
| Flash point                            | No data available        | None known       |
| Autoignition temperature               | No data available        | None known       |
| Decomposition temperature              |                          | None known       |
| pH                                     |                          |                  |
| pH (as aqueous solution)               | No data available        | None known       |
| Kinematic viscosity                    | No data available        | None known       |
| Dynamic viscosity                      | No data available        | None known       |
| Water solubility                       | Miscible in water        |                  |
| Solubility(ies)                        | No data available        | None known       |
| Partition coefficient                  | No data available        | None known       |
| Vapour pressure                        | No data available        | None known       |
| Relative density                       | No data available        | None known       |
| Bulk density                           | No data available        |                  |
| Liquid Density                         | No data available        |                  |
| Vapour density                         | No data available        | None known       |
| Particle characteristics               |                          |                  |
| Particle Size                          | No information available |                  |
| Particle Size Distribution             | No information available |                  |

### 9.2. Other information

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

|            |                           |
|------------|---------------------------|
| Reactivity | No information available. |
|------------|---------------------------|

### 10.2. Chemical stability

|           |                                 |
|-----------|---------------------------------|
| Stability | Stable under normal conditions. |
|-----------|---------------------------------|

#### Explosion data

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

### 10.3. Possibility of hazardous reactions

|                                    |                               |
|------------------------------------|-------------------------------|
| Possibility of hazardous reactions | None under normal processing. |
|------------------------------------|-------------------------------|

### 10.4. Conditions to avoid

|                     |   |
|---------------------|---|
| Conditions to avoid | None known based on information supplied. |
|---------------------|---|

### 10.5. Incompatible materials

**Incompatible materials** None known based on information supplied.

#### 10.6. Hazardous decomposition products

**Hazardous decomposition products** None known based on information supplied.

### **SECTION 11: Toxicological information**

#### 11.1. Toxicological information

##### Information on likely routes of exposure

##### **Product Information**

|                     |   |
|---------------------|---|
| <b>Inhalation</b>   | Specific test data for the substance or mixture is not available. |
| <b>Eye contact</b>  | Specific test data for the substance or mixture is not available. |
| <b>Skin contact</b> | Specific test data for the substance or mixture is not available. |
| <b>Ingestion</b>    | Specific test data for the substance or mixture is not available. |

##### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

##### Acute toxicity

##### **Numerical measures of toxicity**

##### **Component Information**

| Chemical name                  | Oral LD50                                      | Dermal LD50            | Inhalation LC50         |
|--------------------------------|--|------------------------|-------------------------|
| 3(2H)-Isothiazolone, 2-methyl- | 232 - 249 mg/kg ( Rat )<br>= 120 mg/kg ( Rat ) | = 200 mg/kg ( Rabbit ) | = 0.11 mg/L ( Rat ) 4 h |

##### Delayed and immediate effects as well as chronic effects from short and long-term exposure

|  |                           |
|--|---------------------------|
| <b>Skin corrosion/irritation</b>         | No information available. |
| <b>Serious eye damage/eye irritation</b> | No information available. |
| <b>Respiratory or skin sensitisation</b> | No information available. |
| <b>Germ cell mutagenicity</b>            | No information available. |
| <b>Carcinogenicity</b>                   | No information available. |
| <b>Reproductive toxicity</b>             | No information available. |

|                          |                           |
|--------------------------|---------------------------|
| STOT - single exposure   | No information available. |
| STOT - repeated exposure | No information available. |
| Aspiration hazard        | No information available. |
| Other adverse effects    | No information available. |

## SECTION 12: Ecological information

### 12.1. Toxicity

|                          |   |
|--------------------------|---|
| Ecotoxicity              | Harmful to aquatic life.  |
| Unknown aquatic toxicity | Contains 0 % of components with unknown hazards to the aquatic environment. |

### 12.2. Persistence and degradability

|                               |                           |
|-------------------------------|---------------------------|
| Persistence and degradability | No information available. |
|-------------------------------|---------------------------|

### 12.3. Bioaccumulative potential

#### Bioaccumulation

#### Component Information

| Chemical name                  | Partition coefficient |
|--------------------------------|-----------------------|
| 3(2H)-Isothiazolone, 2-methyl- | -0.26                 |

### 12.4. Mobility in soil

|                  |                           |
|------------------|---------------------------|
| Mobility in soil | No information available. |
|------------------|---------------------------|

### 12.5. Results of PBT and vPvB assessment

#### PBT and vPvB assessment

| Chemical name                  | PBT and vPvB assessment         |
|--------------------------------|---------------------------------|
| 3(2H)-Isothiazolone, 2-methyl- | The substance is not PBT / vPvB |

### 12.6. Endocrine disrupting properties

No information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

|                                     |   |
|-------------------------------------|---|
| Waste from residues/unused products | 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

#### IATA

|                              |               |
|------------------------------|---------------|
| 14.1 UN number or ID number  | Not regulated |
| 14.2 UN proper shipping name | Not regulated |

|                                    |                |
|------------------------------------|----------------|
| 14.3 Transport hazard class(es)    | Not regulated  |
| 14.4 Packing group                 | Not regulated  |
| 14.5 Environmental hazards         | Not applicable |
| 14.6 Special Precautions for Users |                |
| Special Provisions                 | None           |

**IMDG**

|  |                          |
|--|--------------------------|
| 14.1 UN number or ID number                                  | Not regulated            |
| 14.2 UN proper shipping name                                 | Not regulated            |
| 14.3 Transport hazard class(es)                              | Not regulated            |
| 14.4 Packing group   | Not regulated            |
| 14.5 Environmental hazards                                   | Not applicable           |
| 14.6 Special Precautions for Users                           |                          |
| Special Provisions   | None                     |
| 14.7 Maritime transport in bulk according to IMO instruments | No information available |

**RID**

|                                    |                |
|------------------------------------|----------------|
| 14.1 UN number                     | Not regulated  |
| 14.2 UN proper shipping name       | Not regulated  |
| 14.3 Transport hazard class(es)    | Not regulated  |
| 14.4 Packing group                 | Not regulated  |
| 14.5 Environmental hazards         | Not applicable |
| 14.6 Special Precautions for Users |                |
| Special Provisions                 | None           |

**ADR**

|                                    |                |
|------------------------------------|----------------|
| 14.1 UN number or ID number        | Not regulated  |
| 14.2 UN proper shipping name       | Not regulated  |
| 14.3 Transport hazard class(es)    | Not regulated  |
| 14.4 Packing group                 | Not regulated  |
| 14.5 Environmental hazards         | Not applicable |
| 14.6 Special Precautions for Users |                |
| Special Provisions                 | None           |

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### National regulations

##### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

##### Persistent Organic Pollutants

Not applicable

##### Export Notification requirements

Not applicable

##### Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

##### The Ozone-Depleting Substances Regulations 2015

Not applicable

##### The Biocidal Products Regulations 2001 (as amended)

| Chemical name                              | The Biocidal Products Regulations 2001 (as amended)  |
|--|--|
| 3(2H)-Isothiazolone, 2-methyl- - 2682-20-4 | Product-type 6: Preservatives for products during storage<br>PT13 - Working or cutting fluid preservatives |



|  |   |
|--|---|
|  | PT12 - Slimicides<br>PT11 - Preservatives for liquid-cooling and processing systems |
|--|---|

**The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)**

Not applicable

**Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)**

Not applicable

**International Inventories**

Contact supplier for inventory compliance status

**15.2. Chemical safety assessment****Chemical Safety Report**

No information available

**SECTION 16: Other information****Key or legend to abbreviations and acronyms used in the safety data sheet****Full text of H-Statements referred to under section 3**

EUH071 - Corrosive to the respiratory tract

H301 - Toxic if swallowed

H311 - Toxic in contact with skin

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H330 - Fatal if inhaled

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

**Legend**

SVHC: Substances of Very High Concern for Authorisation:

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

\*

Skin designation

+ Sensitisers

**Classification procedure**

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Method Used

Acute oral toxicity

Calculation method

Acute dermal toxicity

Calculation method

Acute inhalation toxicity - gas

Calculation method

Acute inhalation toxicity - vapour

Calculation method

Acute inhalation toxicity - dust/mist

Calculation method

Skin corrosion/irritation

Calculation method

Serious eye damage/eye irritation

Calculation method

Respiratory sensitisation

Calculation method

Skin sensitisation

Calculation method

Mutagenicity

Calculation method

Carcinogenicity

Calculation method

Reproductive toxicity

Calculation method

STOT - single exposure

Calculation method

STOT - repeated exposure

Calculation method

Acute aquatic toxicity

Calculation method

Chronic aquatic toxicity

Calculation method

Aspiration hazard

Calculation method

Ozone

Calculation method

**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)  
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)  
European Chemicals Agency (ECHA) (ECHA\_API)  
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)  
National Institute of Technology and Evaluation (NITE)  
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  
World Health Organization

**Revision date** 15-Jun-2023

**Revision Note** Reviewed existing information and made minor updates

**This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended)**  
**Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

#### 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**