



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 16-Mar-2023

Revision Number 2.2

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

1.1. Product identifier

Product Name BioPlex 2200 Syphilis IgM Control Set

Catalogue Number(s) 6631530

Pure substance/mixture Mixture

Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone

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

Recommended use No information available

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
Ireland: Techsupport.UK@bio-rad.com
India: support.india@bio-rad.com
South Africa: cdg_techsupport_eemea@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Ireland: 353-19014670
CHEMTREC India: 000-800-100-7141
CHEMTREC South Africa: 0-800-983-611

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

| | |
|--------------------|----------------------|
| Skin sensitisation | Category 1A - (H317) |
|--------------------|----------------------|

| | |
|--------------------------|---------------------|
| Chronic aquatic toxicity | Category 3 - (H412) |
|--------------------------|---------------------|

2.2. Label elements

Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone

**Signal word**

Warning

Hazard statements

H317 - May cause an allergic skin reaction

H412 - Harmful to aquatic life with long lasting effects

EUH210 - Safety data sheet available on request

Precautionary Statements - EU (§28, 1272/2008)

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P273 - Avoid release to the environment

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

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

2.3. Other hazards

Harmful to aquatic life.

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

| Chemical name | Weight-% | REACH registration number | EC No (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|--|-----------------|---------------------------|---------------------|--|---|----------|----------------------|
| Sodium benzoate 532-32-1 | 0.1 - 0.299 | No data available | 208-534-8 | No data available | - | - | - |
| 5-Chloro-2-methyl-3 (2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 | 0.001 - 0.01 | No data available | - | Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) | Eye Irrit. 2 :: 0.06%≤C<0.6% Skin Corr. 1C :: C≥0.6% Skin Irrit. 2 :: 0.06%≤C<0.6% Skin Sens. 1A :: C≥0.0015% Eye Dam. 1 :: C≥0.6% | 100 | 100 |

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

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapour - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|--|-----------------|-------------------|---|--|--------------------------------------|
| Sodium benzoate 532-32-1 | 4070 | No data available | No data available | No data available | No data available |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 | 53 | 87.12 | No data available | No data available | No data available |

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|-----------------------|---|
| General advice | Show this safety data sheet to the doctor in attendance. |
| Inhalation | Remove to fresh air. |
| Eye contact | 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. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor. |
| Ingestion | Call a doctor. Contains human source material and / or potentially infectious components. |

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

| | |
|-----------------|-------------------------|
| Symptoms | Itching. Rashes. Hives. |
|-----------------|-------------------------|

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

| | |
|------------------------|---|
| Note to doctors | May cause sensitisation in susceptible persons. Treat symptomatically. 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 | Product is or contains a sensitiser. May cause sensitisation by skin contact. |
|---|---|

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 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.

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 Clean contaminated surface thoroughly. Use: Disinfectant.

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 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.

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

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. 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

| Chemical name | European Union | Austria | Belgium | Bulgaria | Croatia |
|--|----------------|--|---|--|----------------|
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 | - | TWA: 0.05 mg/m ³ Skin sensitizer | - | - | - |
| Chemical name | France | Germany TRGS | Germany DFG | Greece | Hungary |
| Sodium benzoate 532-32-1 | - | TWA: 10 mg/m ³ H* | TWA: 10 mg/m ³ Peak: 20 mg/m ³ * | - | - |
| Chemical name | Portugal | Romania | Slovakia | Slovenia | Spain |
| Sodium benzoate 532-32-1 | - | - | - | TWA: 10 mg/m ³ STEL: 20 mg/m ³ * | - |
| Chemical name | Sweden | | Switzerland | | United Kingdom |
| Sodium benzoate 532-32-1 | - | | TWA: 0.2 ppm TWA: 1 mg/m ³ TWA: 10 mg/m ³ STEL: 0.8 ppm STEL: 4 mg/m ³ STEL: 20 mg/m ³ H* | | - |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 | - | | TWA: 0.2 mg/m ³ STEL: 0.4 mg/m ³ | | - |

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)

8.2. Exposure controls**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.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state No information available

Appearance Liquid

Colour amber

Odour No information available.
Odour threshold No information available

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|---|--------------------------|--------------------------|
| 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 | No information available |
| 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 1 | | 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

9.2.1. Information with regards to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

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. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

| | |
|---------------------|---|
| Inhalation | Specific test data for the substance or mixture is not available. |
| Eye contact | Specific test data for the substance or mixture is not available. |
| Skin contact | May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). |
| Ingestion | Specific test data for the substance or mixture is not available. |

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Acute toxicity**Numerical measures of toxicity****Component Information**

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|--|----------------------|--------------------------|-----------------|
| Sodium benzoate | = 4070 mg/kg (Rat) | - | - |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone | = 53 mg/kg (Rat) | = 87.12 mg/kg (Rabbit) | - |

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

| | |
|--|--------------------------------------|
| Skin corrosion/irritation | No information available. |
| Serious eye damage/eye irritation | No information available. |
| Respiratory or skin sensitisation | May cause an allergic skin reaction. |
| Germ cell mutagenicity | No information available. |
| Carcinogenicity | No information available. |
| Reproductive toxicity | No information available. |

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicity Contains 0.1 % of components with unknown hazards to the aquatic environment.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|-----------------|----------------------|---|----------------------------|-------------------------------------|
| Sodium benzoate | - | LC50: 420 - 558mg/L (96h, Pimephales promelas) LC50: >100mg/L (96h, Pimephales promelas) | - | EC50: <650mg/L (48h, Daphnia magna) |

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

| Chemical name | Partition coefficient |
|--|-----------------------|
| Sodium benzoate | -2.13 |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone | 0.7 |

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

| Chemical name | PBT and vPvB assessment |
|--|---------------------------------|
| Sodium benzoate | The substance is not PBT / vPvB |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone | The substance is not PBT / vPvB |

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

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**Germany**

Water hazard class (WGK) obviously hazardous to water (WGK 2)

European Union

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.

Authorisations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

| Chemical name | Restricted substance per REACH Annex XVII | Substance subject to authorisation per REACH Annex XIV |
|---|---|--|
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9 | 75. | - |

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Biocidal Products Regulation (EU) No 528/2012 (BPR)**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

H331 - Toxic 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

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 Note Significant changes throughout SDS. Review all sections

Revision date 16-Mar-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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