

SAFETY DATA SHEET

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

Revision date 12-Jan-2023 Revision Number 2

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

1.1. Product identifier

Product Name BioPlex 2200 HSV-1 & HSV-2 IgG Control Set

Catalogue Number(s) 6633330

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 <u>Manufacturer</u>

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

Chronic aquatic toxicity Category 3 - (H412)

2.2. Label elements

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Hazard statements

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements

P501 - Dispose of contents/ container to an approved waste disposal plant

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

2.3. Other hazards

Harmful to aquatic life.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

| Component | Description |
|------------------|--|
| Positive Control | BioPlex 2200 HSV-1 & HSV-2 IgG Positive Control - Two (2) 1.5 mL vials. The positive controls are provided in a human serum matrix made from defibrinated plasma with added antibodies to HSV-1 and HSV-2 derived from human disease state plasma. All controls contain preservatives including ≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate |
| Negative Control | BioPlex 2200 HSV-1 & HSV-2 IgG Negative Control - Two (2) 1.5 mL vials. The negative controls are |
| | provided in a human serum matrix made from defibrinated plasma. All controls contain preservatives including ≤ 0.3% ProClin 300, < 0.1% sodium azide and ≤ 0.1% sodium benzoate |

| Chemical name | Weight-% | EC No (EU | UK REACH | Classification | Specific | M-Factor | M-Factor |
|-----------------------|--------------|-----------|--------------|----------------|---------------|----------|-------------|
| | | Index No) | registration | according to | concentration | | (long-term) |
| | | | number | GB CLP (SI | limit (SCL) | | |
| | | | | 2020/1567 as | | | |
| | | | | amended) | | | |
| Sodium azide | 0.01 - 0.099 | 247-852-1 | - | (EUH032) | - | - | - |
| 26628-22-8 | | | | Acute Tox. 2 | | | |
| | | | | (H300) | | | |
| | | | | Aquatic Acute | | | |
| | | | | 1 (H400) | | | |
| | | | | Aquatic | | | |
| | | | | Chronic 1 | | | |
| | | | | (H410) | | | |
| 5-Chloro-2-methyl-3(| 0.001 - 0.01 | - | - | (EUH071) | - | 100 | 100 |
| 2H)-isothiazolone, | | | | Acute Tox. 3 | | | |
| mixture with | | | | (H301) | | | |
| 2-methyl-3(2H)-isothi | | | | Acute Tox. 2 | | | |
| azolone | | | | (H310) | | | |
| 55965-84-9 | | | | Acute Tox. 2 | | | |
| | | | | (H330) | | | |
| | | | | Skin Corr. 1C | | | |
| | | | | (H314) | | | |
| | | | | Eye Dam. 1 | | | |
| | | | | (H318) | | | |
| | | | | Skin Sens. 1A | | | |
| | | | | (H317) | | | |
| | | | | Aquatic Acute | | | |
| | | | | 1 (H400) | | | |
| | | | | Aquatic | | | |
| | | | | Chronic 1 | | | |
| | | | | (H410) | | | |

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

This product does not contain candidate substances of very high concern at a concentration >= 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.

Skin contact In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and

water.

Ingestion Contains human source material and / or potentially infectious components.

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 doctorsContains 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.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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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.

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

| Chemical name | United Kingdom |
|---------------|-----------------------------|
| Sodium azide | TWA: 0.1 mg/m ³ |
| 26628-22-8 | STEL: 0.3 mg/m ³ |
| | Sk* |

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 controlsNo information available.

Personal protective equipment

Eye/face protection No special protective equipment required.

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No special protective equipment required. Skin and body protection

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

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

No data available Melting point / freezing point 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 No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known **Autoignition temperature** No data available None known **Decomposition temperature**

None known

pH (as aqueous solution) No data available None known Kinematic viscosity No data available None known No data available **Dynamic viscosity** 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 No data available Relative density 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

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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions
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.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Metals.

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

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 Specific test data for the substance or mixture is not available.

Ingestion 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

No information available

- 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

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------------------------|------------------|------------------------|-----------------------------|
| Sodium azide | = 27 mg/kg (Rat) | = 20 mg/kg (Rabbit) | 0.054 - 0.52 mg/L (Rat) 4 h |
| | | | . , , |
| 5-Chloro-2-methyl-3(2H)-isothia | = 53 mg/kg (Rat) | = 87.12 mg/kg (Rabbit) | - |
| zolone, mixture with | | | |
| 2-methyl-3(2H)-isothiazolone | | | |

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

Skin corrosion/irritationNo information available.

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Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

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.

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to | Crustacea |
|---------------|----------------------|-----------------------|----------------|-----------|
| | | | microorganisms | |
| Sodium azide | - | LC50: =0.8mg/L (96h, | - | - |
| | | Oncorhynchus mykiss) | | |
| | | LC50: =0.7mg/L (96h, | | |
| | | Lepomis macrochirus) | | |
| | | LC50: =5.46mg/L (96h, | | |
| | | Pimephales promelas) | | |

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

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

12.4. Mobility in soil

Mobility in soil No information available.

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12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo information available.

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

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. Flush pipes with water frequently if discarding solutions containing Sodium azide into metal piping systems.

Contaminated packaging

Do not reuse empty containers.

SECTION 14: Transport information

| | - | _ | | |
|---|---|---|-----|--|
| ı | Λ | | ι Λ | |
| | | | | |

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated Not regulated Not applicable

14.6 Special Precautions for Users

Special Provisions None

<u>IMDG</u>

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk No information available

according to IMO instruments

<u>RID</u>

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot 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 |

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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) |
|---|---|
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with | PT02 - Disinfectants and algaecides not intended for direct |
| 2-methyl-3(2H)-isothiazolone - 55965-84-9 | application to humans or animals |
| | PT06 - Preservatives for products during storage |
| | PT13 - Working or cutting fluid preservatives |
| | PT04 - Food and feed area |
| | PT11 - Preservatives for liquid-cooling and processing |
| | systems |
| | PT12 - Slimicides |

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

<u>International Inventories</u> 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

EUH032 - Contact with acids liberates very toxic gas

EUH071 - Corrosive to the respiratory tract

H300 - Fatal if swallowed

H301 - Toxic if swallowed

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H310 - Fatal 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 12-Jan-2023

Revision Note Reviewed existing information and made minor updates

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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

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