

Revision date 12-Jan-2023

Revision Number 3

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

Product identifier

Product Name BioPlex 2200 Celiac IgG Calibrator Set

Catalogue Number(s) 6632200

Other means of identification

Pure substance/mixture Mixture

Recommended use of the chemical and restrictions on use

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

Uses advised against No information available

Details of manufacturer or importer

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 Pty Ltd
u1A, 62 Ferndell Street,
South Granville NSW 2142
Australia

For further information, please contact

Technical Service +61 2 9914 2800 or 1800 224 354
sales.australia@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Australia: 61-290372994

Emergency telephone number No information available

SECTION 2: Hazards identification

GHS Classification

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

Label elements



Signal word

Warning

Hazard statements

H317 - May cause an allergic skin reaction

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

Precautionary Statements - 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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other hazards which do not result in classification

Harmful to aquatic life with long lasting effects Harmful to aquatic life

General Hazards

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients**Substance**

Not applicable

Mixture

| Component | Description |
|-----------|--|
| CAL | BioPlex 2200 Celiac IgG: Nine (9) 0.5 mL vials for anti-tissue Transglutaminase (tTG) and anti-deamidated gliadin peptide (DGP) IgG. The calibrators contain MOPS (3-[N-Morpholino] propanesul-fonic acid) buffer supplemented with protein stabilizer (porcine and human for Celiac IgG.), with added known analyte concentrations derived from human disease state plasma. All Calibrators contain preservatives including $\leq 0.3\%$ ProClin 300, $< 0.1\%$ sodium azide and $\leq 0.1\%$ sodium benzoate |

| Chemical name | CAS No | Weight-% |
|--|-------------|--------------|
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone | 55965-84-9 | 0.001 - 0.01 |
| Non-hazardous ingredients | Proprietary | Balance |

SECTION 4: First aid measures**Description of first aid measures****General advice**

Show this safety data sheet to the doctor in attendance.

Emergency telephone number

Poisons Information Centre, Australia: 13 11 26

Poisons Information Centre, New Zealand: 0800 764 766

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.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives.

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

Suitable 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

Specific hazards arising from the chemical Product is or contains a sensitiser. May cause sensitisation by skin contact.

Special protective actions for fire-fighters

Special protective equipment 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

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.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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.

Precautions to prevent secondary hazards

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

SECTION 7: Handling and storage

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.

Conditions for safe storage, including any incompatibilities

Storage Conditions 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**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

Appropriate engineering controls

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.

Environmental exposure controls No information available.

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

Physical state Liquid
Appearance aqueous solution
Colour amber
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 | | None known |
| Kinematic viscosity | No data available | None known |
| Dynamic viscosity | No data available | None known |
| Explosive properties | Not applicable | |
| Oxidising properties | Not applicable | |
| <u>Other information</u> | | |
| Molecular weight | Not applicable | |
| VOC content | Not applicable | |

SECTION 10: Stability and reactivity

Reactivity

Reactivity No information available.

Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

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.

Conditions to avoid

Conditions to avoid None known based on information supplied.

Incompatible materials

Incompatible materials Metals.

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

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 | Itching. Rashes. Hives. |

Numerical measures of toxicity - Product Information

0.005 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
 1.005 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
 1.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
 1.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour)
 1.005 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

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

See section 16 for terms and abbreviations

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

| | |
|--|---|
| 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. |
| STOT - single exposure | Based on available data, the classification criteria are not met. |
| STOT - 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**Ecotoxicity**

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicity 0.005 % of the mixture consists of component(s) of unknown hazards to the aquatic environment.

Persistence and degradability

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

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

Mobility

Mobility in soil No information available.

Mobility No information available.

Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations**Waste treatment methods**

Waste from residues/unused products 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.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

ADG Not regulated

IATA Not regulated

IMDG Not regulated

Transport in bulk according to Annex II of MARPOL and the IBC Code
No information available

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture**National regulations****Australia**

See section 8 for national exposure control parameters

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

No poisons schedule number allocated

International Inventories

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 Reformatted and updated existing information.

Key or legend to abbreviations and acronyms used in the safety data sheet**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