

SAFETY DATA SHEET

Legal Entity / Contact Address

Montreal, Quebec H4R 2E9

2403 Guenette

Canada

Bio-Rad Laboratories (Canada) Ltd.

This safety data sheet was created pursuant to the requirements of: Canada WHMIS 2015 which includes the amended Hazardous Products Act (HPA) and the Hazardous Products Regulation (HPR)

Revision date 12-Jan-2023 Revision Number 3

1. Identification

Product identifier

Product Name BioPlex 2200 Celiac IgA Calibrator Set

Other means of identification

Catalog Number(s) 6632300

Recommended use of the chemical and restrictions on use

In vitro diagnostic Recommended use

Restricted to professional users

Use according to package label instructions

Restrictions on use No information available

Details of the supplier of the safety data sheet

Corporate Headquarters Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive

Hercules, CA 94547

USA

Manufacturer Address **Bio-Rad Laboratories** 6565-185th Ave NE Redmond, WA 98052

USA

Technical Service 1-800-361-1808

CSD_Techsupport@bio-rad.com

Emergency telephone number

2. Hazard(s) identification

Classification

Skin sensitization Category 1A

Label elements

Warning

Hazard statements

May cause an allergic skin reaction



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Precautionary Statements - Prevention

Avoid breathing dust/fume/gas/mist/vapors/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)

Skin

IF ON SKIN: Wash with plenty of water and soap
If skin irritation or rash occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

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

- 2.405 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
- 3.405 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
- 3.405 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 3.405 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
- 3.405 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. Composition/information on ingredients

Substance

Not applicable.

<u>Mixture</u>

The product contains no substances which at their given concentration, are considered to be hazardous to health

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

| Chemical name | CAS No | Weight-% | Hazardous Material | Date HMIRA filed and |
|---|------------|--------------|------------------------|------------------------|
| | | | Information Review Act | date exemption granted |
| | | | registry number | (if applicable) |
| | | | (HMIRA registry #) | |
| Sodium azide | 26628-22-8 | 0.01 - 0.099 | - | |
| 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with | 55965-84-9 | 0.001 - 0.01 | - | |
| 2-methyl-3(2H)-isothiazolone | | | | |

4. First-aid measures

Description of first aid measures

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

Inhalation Remove to fresh air.

Eye contactContains 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 physician.

Skin contact Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation

or allergic reactions see a physician. Wash skin with soap and water.

Ingestion Call a physician. 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 physicians May cause sensitization in susceptible persons. Treat symptomatically. Contains human

source material and / or potentially infectious components.

5. Fire-fighting measures

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 sensitizer. May cause sensitization by skin contact.

Explosion data

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

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

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.

Methods and material for containment and cleaning up

Methods for containmentDo not allow into any sewer, on the ground or into any body of water.

Methods for cleaning upClean contaminated surface thoroughly. Use:. Disinfectant.

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 before reuse.

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.

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.

| Chemical name | Alberta | British Columbia | Ontario | Quebec |
|---------------|---------------------------------|---------------------------------|-----------------------------|---------------------------------|
| Sodium azide | Ceiling: 0.29 mg/m ³ | Ceiling: 0.29 mg/m ³ | CEV: 0.29 mg/m ³ | Ceiling: 0.29 mg/m ³ |
| 26628-22-8 | Ceiling: 0.11 ppm | Ceiling: 0.11 ppm | CEV: 0.11 ppm | Ceiling: 0.11 ppm |
| | STEL: 0.3 mg/m ³ | | | |

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).

Hand protection Wear suitable gloves.

Skin and body protectionWear 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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid

Appearance aqueous solution

Color amber

Odor No information available No information available

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

Melting point / freezing point

No data available

None known

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Evaporation rateNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility Miscible in water

Solubility in other solventsNo data availableNone knownPartition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNone known

Kinematic viscosity

No data available

None known

No data available

None known

Other information

Explosive propertiesNot applicable.Oxidizing propertiesNot applicable.Softening pointNot applicableMolecular weightNot applicableVOC contentNot applicable

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

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 None known based on information supplied.

Incompatible materials Metals.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

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

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

Skin contact May cause sensitization 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

2.405 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

3.405 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

3.405 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

3.405 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

3.405 % 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 |
| 26628-22-8 | | | - |
| 5-Chloro-2-methyl-3(2H)-isothia | = 53 mg/kg (Rat) | = 87.12 mg/kg (Rabbit) | - |
| zolone, mixture with | | | |
| 2-methyl-3(2H)-isothiazolone | | | |
| 55965-84-9 | | | |

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

Skin corrosion/irritationBased 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 sensitization May cause sensitization 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 exposureBased on available data, the classification criteria are not met.

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

12. Ecological information

Ecotoxicity

Harmful to aquatic life with long lasting effects.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|---------------|----------------------|-----------------------|----------------------------|-----------|
| Sodium azide | _ | LC50: =0.8mg/L (96h, | - | _ |
| 26628-22-8 | | Oncorhynchus mykiss) | | |
| 20020-22-0 | | LC50: =0.7mg/L (96h, | | |
| | | • · · · | | |
| | | Lepomis macrochirus) | | |
| | | LC50: =5.46mg/L (96h, | | |
| | | Pimephales promelas) | | |

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Component Information

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

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properties -

2-methyl-3(2H)-isothiazolone 55965-84-9

Other adverse effects No information available.

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.

14. Transport information

TDG Not regulated

DOT Not regulated

15. Regulatory information

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

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

International Inventories

Contact supplier for inventory compliance status

16. Other information

NFPA Health hazards 2 Flammability 0 Instability 0 Physical and chemical

HMIS Health hazards 2 Flammability 0 Physical hazards 0 Personal protection X

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

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

Australia 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)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

RTECS (Registry of Toxic Effects of Chemical Substances)

World Health Organization

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

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Revision Note Reformatted and updated existing information.

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