

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Rev.1

Effective Date: 13-May-2022

1. PRODUCT AND COMPANY INFORMATION.

Product Name	PictArray™ SARS-CoV-2 ELISA
Product Number	PICT-COV-IgG
Relevant identified uses of the substance or mixture and uses advised against Identified use(s)	In vitro diagnostic medical device. For professional use only.
Company	Pictor Limited 24 Balfour Road Parnell Auckland 1052 New Zealand
Technical Phone	+64 9 309 0950
E-mail	info@pictordx.com

2. COMPOSITION/ HAZARDS INFORMATION ON INGREDIENTS

The hazards identified with this kit are those associated with the following substances. For additional information, please refer to the individual material safety data sheet(s).

Mixtures

Description:	In vitro diagnostic medical device.
Dangerous components:	The product does not contain reportable quantities of dangerous components.
Additional information	None.

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Kit Components

The components contain non-hazardous substances listed in the Table below

Sr. no	Component	Hazardous substance	% By weight
1	PictArray™ SARS-CoV-2 ELISA	None	N/A
2	Sample Diluent	None	N/A
3	Wash Buffer	None	N/A
4	Peroxidase Conjugated anti-Human IgG	Sodium Azide	<0.01
5	TMB Substrate	None	N/A
6	Anti-SP Protein control	None	N/A
7	Anti-NP Protein control	None	N/A

3. HAZARDS IDENTIFICATION

Classification of the substance or mixture
Regulation (EC) No. 1272/2008 (CLP)

Not Classified as hazardous

Emergency Overview

OSHA Hazards

No known OSHA hazards

Not a dangerous substance according to GHS.

Label elements

No Measures Required

Other Hazards

None

HMIS Classification

Health Hazards: 0
Flammability: 0
Physical hazards: 0

NFPA Rating

Flammability: 0
Fire: 0
Reactivity: 0

Potential Health Effects

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Skin May be harmful if absorbed through skin. May cause skin irritation.

Eyes May cause eye irritation.

Ingestion May be harmful if swallowed.

4. FIRST AID MEASURES

Skin contact	Rinse with plenty of water. If symptoms arise, call a doctor.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. If symptoms persist, call a doctor.
Ingestion	Wash out mouth with water. Do not induce vomiting without medical care.
Inhalation	Move person to fresh air. If discomfort persists, call a doctor.

Most important symptoms and effects, both acute and delayed :None known.

Indication of the immediate medical attention and special treatment needed :None.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media	Water spray and carbon dioxide (CO ₂) foam.
Special protective equipment	Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:
Avoid dust formation and avoid breathing vapours, mist, or gas.

Environmental precautions:
Do not let product enter drains.

Methods and materials for containment and cleaning up:
Keep in suitable, closed containers for disposal

7. HANDLING AND STORAGE

Handling	Always wear recommended personal protective equipment. Use gloves when handling. No other special handling advice required.
Storage	Store between 2 ° C to 8 ° C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment**Respiratory protection**

Respiratory protection is not required. Where protection from nuisance levels of dusts is desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper gloves removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye/Face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin and body protection

Choose body protection in relation to its type, to the concentration and number of dangerous substances, and to the specific workplace. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures

General industrial hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES**Appearance**

Form	Liquid
Colour	No data available

Safety data

pH	7.5
Melting point/freezing point	No data available
Boiling point	No data available
Flash point	No data available
Ignition temperature	No data available
Autoignition temperature	No data available
Lower explosion limit	No data available
Upper explosion limit	No data available
Vapour pressure	No data available
Density	No data available
Water solubility	No data available
Partial coefficient: n-octanol/water	No data available
Odour	No data available
Odour Threshold	No data available
Evaporation rate	No data available

10. STABILITY AND REACTIVITY**Chemical stability**

Stable under recommended storage conditions.

Possibility of hazardous reactions

No data available

Conditions to avoid

No data available

Materials to avoid

Strong oxidizing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. Nature of decomposition products not known. Other decomposition products- no data available

11. TOXICOLOGICAL INFORMATION**Acute Toxicity****Oral LD50**

No data available

Inhalation LD50

No data available

Dermal LD50

No data available

Other information on acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probably, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity No data available

Teratogenicity No data available

Specific target organ toxicity - single exposure (Globally Harmonized System)
no data available

Specific target organ toxicity -repeated exposure (Globally Harmonized System)
no data available

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12. ECOLOGICAL INFORMATION

Toxicity Data	No data available
Persistence and degradability	No data available
Bio accumulative potential	No data available
Mobility in soil	No data available
PBT and vPBT assessment	No data available
Other adverse effects	No data available

13. DISPOSAL CONSIDERATIONS

Product	Offer surplus and non-recyclable solutions to a licensed disposal company. Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste disposal company for information
European waste catalogue:	18 01 07.
Packaging:	Disposal should be in accordance with local, state, or national legislation. Packaging materials may be recycled. Contact your local service providers for further information.
Contaminated packaging product	Dispose unused product.

14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

Hazard Class	Data not yet available
Subsidiary Class	Data not yet available
Packing Group	Data not yet available

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UN Number	Data not yet available
Transport hazard class(es)	Transport hazard class(es)
Environmental hazards	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

15. REGULATORY INFORMATION

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

In Vitro diagnostics medical devices
98/79/EC.
OSHA Hazard Communication
Standard.
29 CFR 1910.1200 Consumer
Product Safety Regulations 16 CFR 1600
IVD Product Labelling 21 CFR 809.

R-Phrases
R22

Harmful if swallowed



R36

Irritating to eyes



R37

Irritating to the respiratory



R38

Irritating to skin



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S-Phrases
S28**After contact with skin, wash thoroughly with water.****S37/39****Wear gloves and suitable protective clothing.****S45****In case of accident or if you feel unwell, seek immediate medical advice.****16. OTHER INFORMATION**

The information provided in this Material Safety Data Sheet is believed to be accurate and does not purport to be all inclusive and shall be used only as a guide. It is the responsibility of the user to determine applicability of these data to formulate necessary safety precautions. Pictor Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

End of the document.

SARS-CoVID-2 SDS (DOC-1222) Ver. 0

Approved By:

[\(CO-189\) SARS-CoVID-2 SDS](#)

Description

SARS-CoVID-2 SDS

Justification

SARS-CoVID-2 SDS

Assigned To:

Nancy Ahir

Initiated By:

Nancy Ahir

Priority:

Urgent

Impact:

Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Nancy Ahir	May 13, 2022 4:45 PM NZST	CO-189	0	Published