

This document has been prepared in accordance with the SDS requirements of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS Rev. 10, 2023) and the COMMISSION REGULATION (EU) 2020/878.

Version: v1 Effective date: 13 Sep 2024 Supersedes version of: N/A

SECTION 1: Identification of the substance or mixture and of the supplier

1.1 Product identifier

Product form	: Mixture
Product name	: ZIP-CoVx-P2 This SDS covers all the chemical components of ZIP-CoVx-P2 including the cartridge lyophilised assay as well as the buffers in the lysis tube and the dilution tube.
Product code	: P002782

1.2 Other means of identification

Product other names	: ZIP-CoVx-P2 test, ZIP-CoVx-P2 (SARS-CoV-2 test)
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1.3 Recommended use of the chemical and restrictions of use

Recommended use	: The function of the ZIP-CoVx-P2 test is to aid diagnosis of COVID-19 in symptomatic individuals within 7 days of symptom onset. The test is intended for use in dedicated test spaces (e.g. hospital emergency, intensive care, general practice, antiviral treatment clinics, or other sites established for testing purposes). The test can also be used by laboratory-trained professionals in pathology settings.
Restricted use	: No additional information available.

1.4 Supplier's details

Manufacturer/ Supplier Name	: ZIP Diagnostics Pty. Ltd.
Address	: 24 Cromwell St, Collingwood, Victoria, 3066, Australia
Telephone	: +61 (0) 3 8414 5770
Email	: info@zipdiag.com
Website	: www.zipdiag.com

1.5 Emergency phone number

Australian Poisons Information Centre	: 13 11 26
Hours of operation:	24 hours
EU-wide emergency number	: 112
Hours of operation:	24 hours

SECTION 2: Hazards identification

2.1 Classification of the substance/mixture

GHS Rev. 10, 2023	: This product does not meet the criteria for classification in any hazard class according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS Rev. 10, 2023).
Regulation (EC) No. 1272/2008 (CLP)/REACH 1907/2006 [amended by 2020/878]	: This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878.

2.2 Label elements

GHS Rev. 10, 2023	: No label element(s) required.
Regulation (EC) No. 1272/2008 (CLP)/REACH 1907/2006 [amended by 2020/878]	: No label element(s) required.

2.3 Other hazards which do not result in classification

GHS Rev. 10, 2023	: No additional information available.
Regulation (EC) No. 1272/2008 (CLP)/REACH 1907/2006 [amended by 2020/878]	: No additional information available.

SECTION 3: Composition / information on ingredients

3.1 Substances

Chemical identity & concentrations : Not applicable.

3.2 Mixtures

Chemical identity & concentrations : No components need to be disclosed according to the criteria in Globally Harmonized System of Classification and Labelling of Chemicals (GHS Rev. 10, 2023), Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878.

SECTION 4: First-aid measures

4.1 Description of first aid measures

General notes : First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Seek medical advice if feeling unwell.

Following inhalation : Remove person to fresh air and keep comfortable for breathing. Seek medical advice if any discomfort continues.

Following skin contact : Avoid spreading material on unaffected skin. Wash affected area thoroughly with water. Seek medical advice if any discomfort continues. Remove and isolate any contaminated clothing.

Following eye contact : Do not rub your eyes. Rinse eyes cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical advice if any discomfort continues.

Following ingestion : Rinse mouth with water (only if the person is conscious) Do NOT induce vomiting. Do not use mouth-to-mouth method if victim ingested the substance. Seek medical advice immediately if ingested.

4.2 Most important symptoms/effects caused by exposure, acute and delayed

Symptoms/effects after inhalation

Acute : May cause irritation.
Delayed : Not established.

Symptoms/effects after skin contact

Acute : May cause irritation or an allergic skin reaction.
Delayed : Not established.

Symptoms/effects after eye contact

Acute : Liquid splashes in the eye may cause irritation.
Delayed : Not established.

Symptoms/effects after ingestion

Acute : Ingestion may cause nausea and vomiting.
Delayed : Not established.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat based on observed signs and symptoms of distress. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media : Not established.

5.2 Specific hazards arising from the chemical

Hazardous combustion products : Not flammable.
Hazardous decomposition products in case of fire : Not established.

5.3 Special protective equipment and precautions for firefighters

Firefighting instructions : Move containers from fire area, if possible. Keep containers cool with water spray until well after the fire is out. Keep unauthorised personnel out. Exercise caution when fighting any chemical fire. Use firefighting procedures suitable for surrounding area.

Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	: In the event a cartridge or buffer tube is broken, these personal precautions are applicable. Wear appropriate personal protective equipment to prevent any contamination of skin, eyes and personal clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Protective equipment	: Do not attempt to take action (i.e. contain or clean up spills) without suitable protective equipment.
Emergency procedures	: Evacuate unnecessary personnel. Ventilate enclosed areas.

6.2 Environmental precautions

Prevent spills from entering waterways, sewers, basements or confined areas. If large amounts have been spilled, inform the relevant authorities.

6.3 Methods and materials for containment and cleaning up

For containment	: Collect all waste in suitable and labelled containers and dispose according to local, regional, national, and/or international regulations. Prevent, by any means available, spillage from entering drains or water course.
Methods for cleaning up	: Wear gloves and use absorbent material to mop-up the spillage. Thoroughly clean the contaminated area with freshly prepared 10% household chlorine bleach (final concentration of approximately 0.5% sodium hypochlorite) or equivalent. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using a water dampened paper towel to remove bleach residue, followed with a wipe of 80% v/v ethanol or equivalent. Allow the surface to dry completely before proceeding. Place contaminated materials in suitable and labelled containers and dispose according to local, regional, national, and/or international regulations.

6.4 Reference to other sections

Refer to Section 7 for information on safe handling.
Refer to Section 8 for information on personal protection equipment.
Refer to Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling	: Ensure good ventilation of the work area. Wear personal protective equipment (refer to Section 8 – Exposure controls / personal protection). Avoid contact with skin and eyes. Used device to be handled as infectious.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions	: Comply with instructions for use. Keep in original packaging until just before use. Avoid direct light. Do not freeze.
Incompatible materials	: Not established.
Storage temperature	: 2 - 25°C.

SECTION 8: Exposure controls / personal protection

8.1 Control parameters


Occupational exposure limit values or biological limit values	: Not established.
Recommended monitoring procedures	: No additional information available.
Control banding	: No additional information available.

8.2 Appropriate engineering controls

Appropriate engineering controls	: Ensure good ventilation of the work area.
Environmental exposure controls	: Avoid release to the environment. Follow local, regional, national, and/or international regulations for disposal of waste.

8.3 Individual protection measures, such as protective equipment

Personal protective equipment:	: Gloves. Safety glasses. Protective clothing.
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Hand protection:	: Wear chemical-resistant gloves made of any waterproof material.
Eye protection:	: Wear primary eye protection such as safety glasses with a secondary protection face shield (recommended when working with potentially infectious biological samples). Provide an emergency eye wash station and quick drench shower in the immediate work area.
Skin and body protection:	: Wear suitable protective clothing. Wash contaminated clothing, separately from other laundry, with detergent and water before reuse.
Respiratory protection:	: An N-95 mask is recommended when working with potentially infectious biological samples.
Personal protective equipment symbol(s):	

SECTION 9: Physical and chemical properties

9.1 information on basic physical and chemical properties

Physical state	: Cartridge assay: solid lyophilised beads. : Buffer in lysis tube: liquid. : Buffer in dilution tube: liquid.
Colour	: Cartridge assay: various. : Buffer in lysis tube: blue, transparent. : Buffer in dilution tube: yellow, transparent.
Odour	: Odourless.
Melting point/freezing point	: Not established.
Boiling point or initial boiling point and boiling range	: Not established.
Flammability	: Non-flammable.
Lower and upper explosion limit/flammability limit	: Not applicable.
Flash point	: Not established.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not established.
pH	: 8.8 for both buffers.
Kinematic viscosity	: Not established.
Solubility	: Lyophilised beads in the cartridge are reconstituted upon buffer addition.
Partition coefficient: n-octanol/water (log value)	: Not established.
Vapour pressure	: Not established.
Density and/or relative density	: Not established.
Relative vapour density	: Not established.
Particle characteristics	: Not established.

9.2 Other information

No additional information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under normal conditions of use, storage and transport.

10.2 Chemical stability

Stable under normal conditions of use, storage and transport.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

None under normal conditions of use and storage (refer to Section 7 – Handling and Storage).

10.5 Incompatible materials

Not established.

10.6 Hazardous decomposition products

Not established.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity	: Not classified according to criteria set in GHS and EU/CLP.
Skin corrosion/irritation	: Not classified according to criteria set in GHS and EU/CLP.
Serious eye damage/irritation	: Not classified according to criteria set in GHS and EU/CLP.
Respiratory/skin sensitization	: Not classified according to criteria set in GHS and EU/CLP.
Germ cell mutagenicity	: Not classified according to criteria set in GHS and EU/CLP.
Carcinogenicity	: Not classified according to criteria set in GHS and EU/CLP.
Reproductive toxicity	: Not classified according to criteria set in GHS and EU/CLP.
Specific target organ toxicity (single exposure)	: Not classified according to criteria set in GHS and EU/CLP.
Specific target organ toxicity (repeated exposure)	: Not classified according to criteria set in GHS and EU/CLP.
Aspiration hazard	: Not classified according to criteria set in GHS and EU/CLP.

11.2 Potential health effects

Refer to Section 4.2.

SECTION 12: Ecological information

12.1 Ecotoxicity (aquatic and terrestrial, where available)

Not established.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

Not established.

12.5 Other adverse effects

No additional information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product waste	: Do not discharge into drains or the environment. Dispose according to local, regional, national, and/or international regulations.
Packaging waste	: Dispose according to local, regional, national, and/or international regulations.

13.2 Other information

Treat all clinical samples, including used test components, as though potentially infectious. Wash hands thoroughly after sample handling and/or testing. Follow your local environmental waste procedures for proper disposal of clinical samples and used test components. These materials may exhibit characteristics of bio- and chemically hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, clinical samples and used test components should be disposed of as per WHO (World Health Organisation) medical waste handling and disposal guidelines.

SECTION 14: Transport information

14.1 UN number

The product is not classified as dangerous for transport.

14.2 UN proper shipping name

The product is not classified as dangerous for transport.

14.3 Transport hazard class(es)

The product is not classified as dangerous for transport.

14.4 Packing group

The product is not classified as dangerous for transport.

14.5 Environmental hazards for transport purposes

The product is not classified as dangerous for transport.

14.6 Transport in bulk according to IMO instruments

Not applicable.

14.7 Special precautions for user

None specified.

SECTION 15: Regulatory information

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

AU regulations : No additional information available.
EU REACH Candidate List (SVHC) : Contains no substance(s) listed on the REACH Candidate List
EU regulations (other) : No additional information available.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

16.1 Training advice

Not applicable

16.2 References used to prepare the SDS

DOCUMENT ID

DOCUMENT TITLE

ECHA-20-H-25-EN

: ECHA Guidance on the compilation of safety data sheets
Version 4.0 December 2020

REGULATION (EC) No. 1272/2008

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 16 December 2008 on classification, labelling and
packaging of substances and mixtures, amending and repealing Directives
67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

NOTE: Referenced as EU/CLP in Section
11.1 – Information on toxicological effects

REGULATION (EC) No. 1907/2006
(REACH)

: REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 18 December 2006 concerning the Registration,
Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing
a European Chemicals Agency, amending Directive 1999/45/EC and repealing
Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No
1488/94 as well as Council Directive 76/769/EEC and Commission Directives
91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

COMMISSION REGULATION (EU)
2020/878

: COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending
Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of
the Council concerning the Registration, Evaluation, Authorisation and
Restriction of Chemicals (REACH)

Safe Work Australia
Last updated: 16 Jun 2023

: Preparation of safety data sheets for hazardous chemicals Code of Practice,
June 2023

ST/SG/AC.10/30/Rev.10

: Globally Harmonized System of Classification and Labelling of Chemicals
(GHS), Tenth revised edition

NOTE: Referenced as GHS in Section
11.1 – Information on toxicological effects

16.3 Definitions

ABBREVIATION

DEFINITION

AU

: Australia

CLP

: Classification, Labelling and Packaging

EC

: European Commission

ECHA

: European Chemicals Agency

EU

: Europe

GHS

: Globally Harmonized System

IMO instruments

: International Maritime Organization instruments

N/A

: Not Applicable

REACH	: Registration, Evaluation, Authorisation and restriction of Chemicals
SDS	: Safety Datasheet
STOT-SE	: Specific Target Organ Toxicity – Single Exposure
SVHC	: Substance of Very High Concern
UN	: United nations
WHO	: World Health Organization

16.4 Revision history

REVISION	DESCRIPTION OF CHANGE	EFFECTIVE DATE
1	First release	14 Sep 2024

16.5 Disclaimer

This information is based on current knowledge and data available and is believed to be correct. This information is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not be construed as guaranteeing any specific property of the product. Caution should be used in handling and use of the product. In the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

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D009195 v1 (Sep 2024)