

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

1.1. Product Identifier:

Product Name IntelliPlex™ SARS-CoV-2 Detection Kit
Product Code 82303-U/82303

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses For professional users only.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier: PlexBio Co., Ltd.
 6F-1, No. 351 Yangguang Street, Neihu District, Taipei 114 Taiwan, R.O.C.
 Tel: +886-2-2627-5878 Fax: +886-2-2627-5979

1.4 Emergency telephone number and email

Emergency Phone # Tel: +886-2-2627-5878
Email service@plexbio.com

SECTION 2: HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients listed in section 3.
 Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008 or 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not a dangerous substance or mixture according to the Globally Harmonized System (GHS).

2.2 GHS Label elements, including precautionary statements:

Not a hazardous substance or mixture.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

None identified. This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Kit Contents	Known Hazardous Components	CAS-No.	Concentration
SARS-CoV-2 KIT Primer Mix	Not Hazardous		
SARS-CoV-2 KIT RT-PCR Enzyme Mix	Glycerol (Not Hazardous)	56-81-5	40-70%
SARS-CoV-2 KIT RT-PCR Buffer	Not Hazardous		
SARS-CoV-2 KIT πCode MicroDisc	Sodium azide	26628-22-8	0.05%
	Glycerol (Not Hazardous)	56-81-5	40-60%
SARS-CoV-2 KIT POS Control	Not Hazardous		
SARS-CoV-2 KIT Extraction Control	Not Hazardous		
NEG Control	Not Hazardous		
Hy Buffer	Not Hazardous		
SA-PE Solution	Sodium azide	26628-22-8	0.05%
10X Wash Buffer	Sodium azide	26628-22-8	0.09%
	Tween 20 (Not Hazardous)	9005-64-5	0.1%
ddH2O	Not Hazardous		

The concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS are present below their cut-off levels. No components need to be disclosed according to the applicable regulations.

Component: Sodium azide		Classification
Formula	NaN ₃	Acute Tox. 2 (H300); Acute Tox. 1 (H310);
Cas-No	26628-22-8	STOT RE 2 (H373); Aquatic Acute 1 (H400);
EC-No	247-852-1	Aquatic Chronic 1 (H410)
Index-No.	011-004-00-7	(EUH032)

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Eye Contact: Flush eyes with water as a precaution. Remove contact lenses. Consult a physician.

Skin Contact: Wash off with soap and plenty of water. Consult a physician.

Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician

Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in section 2, section 3 and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: FIRE AND EXPLOSION DATA

5.1 Extinguishing media

Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Not flammable or combustible.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

Hazardous decomposition products formed under fire conditions: Sodium oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For handling and storage refer to section 7. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Take up mechanically and collect in suitable container for disposal.

6.4 Reference to other sections

For handling and storage refer to section 7. For personal protection see section 8. For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 – Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

7.2 – Conditions for safe storage, including anything that is incompatible

Keep container tightly closed in a dry and well-ventilated place. Refer to product label.

7.3 – Specific end use(s)

Refer to section 1.2

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1 Control parameters
United States of America

Component	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium azide	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm	Skin (Vacated) Ceiling: 0.1 ppm (Vacated) Ceiling: 0.3 mg/m ³	Ceiling: 0.1 ppm Ceiling: 0.3 mg/m ³
Glycerol		(Vacated) TWA: 10 mg/m ³ (Vacated) TWA: 5 mg/m ³ TWA: 15 mg/m ³ TWA: 5 mg/m ³	
TS-769099 (RNAstable LD)	TWA: 10 ppm 25 mg/m ³	TWA: 10 ppm 25 mg/m ³	

ACGIH - American Conference of Governmental Industrial Hygienists
OSHA - Occupational Safety and Health Administration
NIOSH IDLH: NIOSH - National Institute for Occupational Safety and Health
European Union

Component	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium Azide	26628-22-8	TWA	0.1 mg/m ³	2000/39/EC and 2006/15/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative	STEL	0.3 mg/m ³	2000/39/EC and 2006/15/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative	AGW	0.2 mg/m ³	DE TRGS 900
Glycerol	56-81-5	AGW (Inhalable fraction)	200 mg/m ³	DE TRGS 900
		TWA	10 mg/m ³	TLV-ACGIH

8.2 Exposure controls
Appropriate engineering controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below

recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protective equipment

Follow usual standard laboratory practices. Use appropriate chemical resistant gloves, appropriate safety glasses and wear protective work clothing.

Eye Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Hand Protection

Protective gloves (Natural rubber, Nitrile rubber, Neoprene, PVC; Breakthrough time see manufacturers information)

Skin and body protection

Long sleeved clothing

Respiratory protection

When working with concentrations above the exposure limit use engineering controls and air-purifying respirators (full-face particle respirator type N100 (US) or type P3 (EN 143)). Use a full-face supplied air respirator if no engineered controls are utilized. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Environmental exposure controls

Prevent leakage or spillage. Discharge into the environment must be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

SARS-CoV-2 KIT Primer Mix; SARS-CoV-2 KIT RT-PCR Enzyme Mix; SARS-CoV-2 KIT RT-PCR Buffer; SARS-CoV-2 KIT πCode MicroDisc; NEG Control; Hy Buffer; SA-PE solution; 10X Wash Buffer; SARS-CoV-2 KIT Extraction Control; ddH2O

Physical State and Appearance:	Liquid.	Vapor Pressure:	Not available.
Odor:	Not available.	Vapor Density:	Not available.
Taste:	Not available.	Volatility:	Not available.
pH (1% soln/water):	Not available.	Odor Threshold:	Not available.
Boiling Point:	Not available.	Water/Oil Dist. Coeff.:	Not available.
Melting Point:	Not available.	Ionicity (in Water):	Not available.
Critical Temperature:	Not available.	Dispersion Properties:	Not available.
Specific Gravity:	Not available.	Solubility:	Not available.

SARS-CoV-2 KIT POS Control

Physical State and Appearance:	Solid.	Vapor Pressure:	Not available.
Odor:	Not available.	Vapor Density:	Not available.
Taste:	Not available.	Volatility:	Not available.
pH (1% soln/water):	Not available.	Odor Threshold:	Not available.
Boiling Point:	Not available.	Water/Oil Dist. Coeff.:	Not available.
Melting Point:	Not available.	Ionicity (in Water):	Not available.
Critical Temperature:	Not available.	Dispersion Properties:	Not available.
Specific Gravity:	Not available.	Solubility:	Not available.

9.2 Other safety information

Not available

SECTION 10: STABILITY AND REACTIVITY DATA

10.1 Reactivity:	The product is stable under recommended shipping and storage conditions.
10.2 Chemical Stability:	The product is stable under recommended shipping and storage conditions.
10.3 Possibility of hazardous reactions	Will not occur.
10.4 Conditions to Avoid	Excess heat
10.5 Incompatible materials	Strong acids/alkalis, strong oxidizing/reducing agents.
10.6 Hazardous decomposition products	Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
Acute toxicity:	Not classified based on available information.
Ingredients	
Sodium Azide	Acute toxicity LD50 Oral - Rat - 27 mg/kg
Glycerol	Acute toxicity LD50 Oral - Rat - 12600 mg/kg
	LD50 Dermal - Rabbit - > 10000 mg/kg
Tween20	LD50 Oral - Rat - 36700 mg/kg
Eye Contact:	No data available
Skin Contact:	No data available
Inhalation:	No data available
Ingestion:	No data available
Carcinogenic Effects:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, 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 as a known or anticipated carcinogen by NTP. OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
Mutagenic Effects:	No data available
Reproduction Toxicity:	No data available
Sensitization:	No data available
STOT - Single exposure	No data available
STOT - Repeated exposure	No data available
Additional Information:	RTECS: VY8050000; MA8050000; TR7400000

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity:	No data available
12.2 Persistence and degradability:	No data available
12.3 Bioaccumulative potential:	No data available
12.4 Mobility in soil:	No data available

12.5 Results of PBT and vPvB assessment:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
12.6 Other adverse effects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Potentially toxic to aquatic life.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Product: Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

General	The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, DOT, ADR/RID).
14.1 – UN Number	Not applicable
14.2 – Proper shipping name	Not applicable
14.3 – Hazard class	Not applicable
14.4 – Packing group	Not applicable
14.5 – Environmental hazards	Not applicable
14.6 – Special precautions for the user	Not applicable
14.7 – Transport in bulk information	Not applicable

SECTION 15: OTHER REGULATORY INFORMATION**European Union:****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Contains no REACH substances with Annex XVII restrictions. Contains no substance on the REACH candidate list. Contains no REACH Annex XIV substances.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

United States of America:

Regulatory Status Classified in accordance with Appendix A, Appendix B and Appendix F of the OSHA Hazard Communication Standard 29 CFR §1910.1200. Regulatory References OSHA Hazard Communication Standard 29 CFR §1910.1200

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

See section 2 for more information

Clean Water Act/ Clean Air Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act or Clean Air Act.

US State Regulation**State Right to Know:**

Glycerol (CAS-No. 56-81-5) can be found on the following state Right-to-Know lists: Pennsylvania, Minnesota, Massachusetts, New Jersey, Rhode Island

Sodium azide (CAS-No. 26628-22-8) can be found on the following state Right-to-Know lists: Pennsylvania, Minnesota, Massachusetts, New Jersey, Rhode Island

Tween 20 (Cas-No. 9005-64-5) can be found on the following state Right-to-Know lists: Pennsylvania, Minnesota, Massachusetts, New Jersey, Rhode Island

TS-769099 (RNAstable LB) can be found on the following state Right-to-Know lists: Pennsylvania, Minnesota, Massachusetts, New Jersey, Rhode Island

California Directors List of Hazardous Substances

The following ingredients are listed or exempt: TS-769099

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16: OTHER INFORMATION**Full text of H-Statements referred to under section 3.**

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH032 Contact with acids liberates very toxic gas.

To the best of our knowledge, the information contained herein is accurate and complete. However, we can neither guarantee nor assume any liability whatsoever for the accuracy or completeness of the information contained in this MSDS. Final determination of suitability of any material is the sole responsibility of the user, as health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. All materials and mixtures may present unknown hazards and should be used with caution. No warranty is made, either express or implied.