

SECTION 1. IDENTIFICATION**1.1. Product Identifier**

Product Name: **PlexPCR® Flu/RSV/SARS-CoV-2**
Catalogue Number: 1703192
REACH No.: Not applicable, composition is mixture. No registration number is given yet for these substance / substances in this mixture since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

1.2. Product Information

Components: Flu/RSV/SARS-CoV-2; **Plex** Mastermix; Reverse Transcriptase, RNase inhibitor

1.3. Recommended use and restrictions on use

Relevant identified uses: For in vitro diagnostic use, professional uses only

Restrictions on Use: Not for consumer use

1.4. Details of the Supplier of the Safety Data Sheet

Manufacturer: SpeedX Pty. Ltd.
Suite 102
National Innovation Centre
4 Cornwallis Street
Eveleigh, NSW, 2015
Australia
Telephone: +61 (0)2 9209 4170

For further information, please contact:
Email: tech@speedx.com.au
Website: www.plexpcr.com

1.5. Emergency telephone numbers

Emergency telephone: International: +61 (0)2 9209 4169 / For Australia: (02) 9209 4169

SECTION 2. HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008

Components	Form	GHS Classification
Plex Mastermix	Mixture	Chronic aquatic toxicity (Category 4), H413
Flu/RSV/SARS-CoV-2	Mixture	Not hazardous
Reverse Transcriptase	Mixture	Not hazardous
RNase inhibitor	Mixture	Not hazardous

2.2. Labelling elements

Classification according to Regulation (EC) No 1272/2008

GHS Pictogram: None
Signal word: None
Hazard Statement: Not Applicable

Components	Hazard Statements (CLP)	Precautionary Statements (CLP)
Plex Mastermix	H413 – May cause long lasting harmful effects to aquatic life	None
Flu/RSV/SARS-CoV-2	None	None
Reverse Transcriptase,	None	None
RNase inhibitor	None	None

Other substances in the component mixtures do not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ ((EC) No. 1907/2006 (REACH), Article 59). The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contain the resulting labelling for the kit.

2.3. Other hazards

Contains a known or suspected endocrine disruptor.

SECTION 3. HAZARDS IDENTIFICATION

3.1. PlexPCR® Flu/RSV/SARS-CoV-2

Name, synonyms and formulae	Product Identifier	Composition	Classification Regulation (EC) No. 1272/2008 (CLP)
t-ctylphenoxy polyethoxyet hanol 4- (1,1,3,3- Tetramethylbutyl)phenylpo lyethylene glycol Polyethylene glycol tert- octylphenyl ether. (C ₂ H ₄ O) _n C ₁₄ H ₂₂ O	(CAS No.) 9002-93-1 (EC No.) 618-344-0 p-tertiary-Octylphenoxy polyethyl alcohol Included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH)	$\leq 0.025\%$	Acute Tox. 4; - H302, Skin Irrit. 2; Eye Dam. 1; - H318, Aquatic Acute 1; Aquatic Chronic 1; H315, H400, H410 M-Factor - Aquatic Acute: 10 - Aquatic Chronic: 10
Glycerol, C ₃ H ₈ O ₃	(CAS No.) 56-81-5 (EC No.) 200-289-5	$\leq 5\%$	Not a hazardous substance or mixture

SECTION 4. FIRST AID MEASURES

4.1. Description of first aid measure

First-aid measures general	If necessary, consult a physician. Show this safety data sheet to the medical professional in attendance.
First-aid measures after inhalation	Remove to fresh air, keep the patient warm and provide resuscitation if necessary. If symptoms develop, obtain medical attention.
First-aid measures after skin contact	Remove contaminated clothing. Rinse the affected skin or mucous membrane thoroughly under running water. (If possible) use soap.
First-aid measures after eye contact	After contact with the eyes rinse thoroughly with plenty of water for at least 15 minutes with the eyelid wide open.
First-aid measures after ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth and drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling section 2.2 and/or in section 11. Not expected to present a significant hazard under anticipated conditions of normal use.

May cause slight irritation to eyes.

4.3. Indication of any immediate medical attention and special treatment needed

No additional recommendations

SECTION 5. FIREFIGHTING MEASURES**5.1. Extinguisher media**

Fire extinguishers appropriate to the fire classification, and, if applicable, a fire blanket must be available in a prominent location in the work area.

Suitable extinguishing media	All extinguishers like FOAM, WATER SPRAY, DRY POWDER, CARBON DIOXIDE can be used.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture

Fire Hazard	Not flammable.
Hazardous decomposition products in case of fire	Carbon oxides, Nitrogen oxides, Hydrogen chloride gas, Phosphorus oxides, Potassium oxides, Magnesium oxide, Sulphur oxides, Hydrogen sulfide gas, Lithium oxides.

5.3. Advice for firefighters

Firefighting instructions	Product package burns like paper or plastic. Spray any vapours released with water. Retain fire water where possible.
Protection during firefighting	Protective breathing apparatus, independent of the ambient air (isolated equipment), and sealed protective clothing is necessary in the event of large-scale formation of toxic substances.

5.4. Additional information

None.

SECTION 6. ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel	• Evacuate unnecessary personnel. • Ensure adequate ventilation • Avoid contact with skin, eyes and clothing. • Regular staff training is necessary, indicating hazards and precautions on the basis of operating instructions. • Restrictions on activity must be observed.
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For emergency responders

- Wear suitable protective equipment as defined in section 8.
- Prevent further leakage or spillage if safe to do so.
- Avoid release of materials into the environment.

6.2. Environmental precautions

- Prevent further leakage or spillage if safe to do
- Do not let product enter drains
- Do not allow material to contaminate ground water system.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material.

6.4. Reference to other sections

See section 8 for more information.

SECTION 7. HANDLING AND STORAGE
7.1. Precautions for safe handling

Precautions for safe handling	• Handling in accordance with the instructions supplied with the product. • Provide adequate ventilation. • Avoid breathing vapours, mist or gas. • Avoid contact with skin, eyes and clothing.
Hygiene measures	• Handle in accordance with good industrial hygiene and safety practice. Take off contaminated clothing and wash before reuse. • Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	• Keep only in the original container. • Store in a cool well ventilated place out of direct sunlight. Keep container closed when not in use. • Hygroscopic.
Incompatible materials	Store separately from: Bases, oxidizing agents, reducing agents, Alkali metals, Strong acids, Acid chlorides, Phosphorus halides.

7.3. Specific end use(s)

For in vitro diagnostic use, professional use only

SECTION 8. HAZARDS IDENTIFICATION
8.1. Control parameters

Glycerol 56-81-5		
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³
United Kingdom	WEL TWA (ppm)	N/A
United Kingdom	WEL STEL (mg/m ³)	N/A
United Kingdom	WEL STEL (ppm)	N/A



PlexPCR® Flu/RSV/SARS-CoV-2

SAFETY DATA SHEET

In accordance with Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Issuing Date 28/07/2023

United Kingdom	Remark (WEL)	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used.
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol 9002-93-1		
United Kingdom	WEL TWA (mg/m ³)	N/A
United Kingdom	WEL TWA (ppm)	N/A
United Kingdom	WEL STEL (mg/m ³)	N/A
United Kingdom	WEL STEL (ppm)	N/A
United Kingdom	Remark (WEL)	Contains no substances with occupational exposure limit values.

8.2. Exposure controls

Appropriate engineering controls:	Good ventilation or extraction system in the room, floor resistant to chemicals and washing facilities available.
General controls	Avoid all unnecessary exposure. Handle in accordance with good industrial hygiene and safety practice.
Respiratory protection	Respiratory protection is not normally required. For nuisance exposures or if risk assessment is required, use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU) with integrated side shields or wrap-around protection.
Hand protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Wear protective gloves that satisfy the specifications of EU Directive 89/686/EEC and the standard EN374 derived from it. Exact breakthrough times to be found through the manufacturer of the protective gloves and must be observed. Gloves should be removed and replaced if there are any signs of degradation or breakthrough.
Skin and body protection	Wear suitable protective clothing.
Thermal protection	Not required for normal conditions of use.
Environmental exposure controls	Prevent product from entering drains. Do not allow material to contaminate ground water

These recommendations are advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

PlexPCR® Flu/RSV/SARS-CoV-2	
Physical state:	Liquid
Colour:	Colourless
Molecular Mass:	No data available
Odour / Odour threshold	Odourless
pH:	7-9
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point or initial boiling point and boiling range	No data available

PlexPCR® Flu/RSV/SARS-CoV-2	
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	Not applicable
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Density and / or relative density	~1.0 g/cm ³ (Water = 1)
Solubility:	No data available
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Oxidising properties:	None
Explosive properties:	Not classified as explosive

9.2. Other information

Data for the other parameters of the mixtures are not available, because no registration and no chemical safety report is required.

9.3. Relevant Properties of Substance Group

None

SECTION 10. STABILITY AND REACTIVITY**10.1. Reactivity**

None Known.

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reaction has not been reported

10.4. Conditions to avoid

No information available

10.5. Incompatible materials

No dangerous reaction known under normal use condition

10.6. Hazardous decomposition products

No data available

SECTION 11. TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**

Glycerol	
LD50 oral rat	12,600 mg/kg



PlexPCR® Flu/RSV/SARS-CoV-2

SAFETY DATA SHEET

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LC50 inhalation rat 4hr	>2.75 mg/l
LD50 Dermal rabbit	10,000 mg/kg
LD50 Dermal guinea pig	56750 mg/kg
TSCA Inventory:	Listed (1,2,3-Propanetriol)
California Proposition 65 List:	Not listed
Australia NICNAS:	Not listed
Canada CEPA 1999:DSL:	Not listed
Japan CSCL/PRTR:	Not listed
Japan PDSCL:	Not listed
Japan ISHL:	Not listed
South Korea TCCA:	Not listed
Korea Exist.Chem.Inventory:	KE-29297
RTECS:	MA8050000
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol	
LD50 Dermal rabbit	>3000 mg/kg
RTECS:	Not available

Quantitative data on the toxicity of this product is not available.

PlexPCR® Flu/RSV/SARS-CoV-2	
Acute toxicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Carcinogenicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Reproductive toxicity	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure)	Not classified.
Additional information	Based on available data, the classification criteria are not met.
Aspiration hazard	Not classified.

PlexPCR® Flu/RSV/SARS-CoV-2	
Additional information	Based on available data, the classification criteria are not met.
Potential adverse human health effects and symptoms:	Not expected to present a significant hazard under anticipated conditions of normal use.

11.2. Information on other hazards

Endocrine disrupting properties

- Contains a known or suspected endocrine disruptors

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Glycerol	
Ecology - Water	Not Classified
LC50 – Fish (Salmo gairdneri) 96hr	54,000 mg/l
LC50 - Bacteria, activated sludge	> 1,000 mg/l
EC50 – Daphnia (daphnia magna, locomotor effect) 24hr	> 10,000 mg/l
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol	
Ecology - Water	Harmful to aquatic life with long lasting effects. Avoid contact of substance/mixture to environment.
LC50 – Fish Pimephales promelas (fathead minnow) 96hr	4-8.9 mg/l
LC50 - Daphnia magna (Water flea) 48hr	18 - 26 mg/l

Environmental hazards must not be labelled with P phrases until 125 mL or 125 g (EU 1272/2008 Annex I - 1.5.2).

12.2. Persistence and degradability

Glycerol	
Biodegradation	No data available
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol	
Biodegradation	No data available

12.3. Bioaccumulative potential

Glycerol	
Bioconcentration factor (BCF REACH)	No additional information available
Log Pow	-1.76
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol	
Bioconcentration factor (BCF REACH)	No additional information available
Log Pow	No data available

12.4. Mobility in soil

Glycerol	
Ecology - Soil	Miscible with water.
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol	

Ecology - Soil	No data available.
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12.5. Results of PBT and vPvB assessment

Glycerol
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine Disrupting Properties

Assess endocrine disrupting properties for the environment.

Substance identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Contains a substance on the National Authorities Endocrine Disruptor Lists

4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol	
EU - Endocrine Disruptors Candidate List	Group III Chemical
EU - Endocrine Disruptors – Evaluated Substances	-
EU National Authorities Endocrine Disruptor Lists - Environment	List I
Japan - Endocrine Disruptor Information	-

12.7. Other adverse effects

Chemical	Effects
Glycerol	No additional information available.
4-(1,1,3,3-Tetramethylbutyl)phenyl polyethylene glycol	Very toxic to aquatic life with long lasting effects.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste disposal recommendations:	Product Offer surplus and non-recyclable solutions to a licensed disposal company. Contaminated packaging Dispose of as unused product.
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SECTION 14. TRANSPORT INFORMATION

14.1. In accordance with ADR / RID / IMDG / IATA / AND

	ADR	IMDG	IATA	AND	RID
UN-No.	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
Proper shipping name	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
Transport hazard class(es)	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
Packing group	Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

14.2. Marine pollutant

No

14.3. Special precautions for user

Not applicable

14.4. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15. REGULATORY INFORMATION

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

15.1. Substance of Very High Concern

Authorisations and/or restrictions on use:

- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) p-tertiary-Octylphenoxy polyethyl alcohol.
- This product contains a substance listed on Annex XIV of the REACH Regulation (EC) Nr. 1907/2006. Listed substance / Sunset Date: p-tertiary-Octylphenoxy polyethyl alcohol / 04.01.2021.
- After the sunset date the use of this substance requires either an authorization or can only be used for exempted uses, e.g. use in routine analytics or use as intermediate.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16. REGULATORY INFORMATION**16.1. Full text of H, EUH and P statement**

H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

16.2. Training Advice

Regular laboratory and chemical handling safety training

16.3. Abbreviations and acronyms

ADR	Accord européen relatif au transport international des marchandises Dangereuses par Route
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service number
CLP	Classification, Labeling and Packaging
DNEL	Derived No effect Limit
EC	European Community
EC50	Effective Concentration 50%
EN	European Norm
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IMDG	International Maritime Dangerous Goods Code
IMO	International Maritime Organisation
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%

MAC	Maximal Allowed Concentration
O/W	Oil-in-Water (chemistry)
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulative and toxic
PMcc	Pensky-Martens Closed Cup test
PNEC	Predicted no effect concentration
REACH	Registration, Evaluation and Authorisation of CHemicals
RID	Règlement concernant le transport international ferroviaire de marchandises
STEL	Short Term Exposure Limit
TWA	Time Weighted Average
UNXXXX	Number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods
vPvB	Very persistent and very bioaccumulative

16.4. Recommended Restriction on Use

- Only for professional user working under controlled conditions.
- Consider employee restrictions for young people (e.g. 94/33/EC)
- Consider employee restrictions for pregnant women and nursing women (e.g. 92/85/EEC)

16.5. Sources of Key Data

- UK – Control of Substances Hazardous to Health Regulations 2002 (as amended). Health and Safety at Work etc. Act 1974 (as amended). Guidance Workplace Exposure Limits EH40.
- EU – REGULATION (EC) No. 1272/2008 and (EC) No. 1907/2006 (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.
Regulation 453/2010/EU REACH - REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS. Regulation 487/2013/EU, 4th adaptation of CLP regulation to technical and scientific progress. Legislation 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) (as amended). Commission Regulation (EU) No 2015/830 of 28 May 2015.
- USA – Occupational Safety and Health Administration (OSHA) OSHA 29CFR1910.1200, The American Conference of Governmental Industrial Hygienists (ACGIH).
- Australia - Work Health and Safety (WHS) Act, [NOHSC:2011(2003) and NOHSC:1008(2004)]
- Canada – Hazardous Products Regulations SOR/2015-17 and WHMIS 2015

16.6. Other information

SpeedX Pty Ltd, provides the information contained herein in good faith being up to date of own realizations at revision time. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly and professionally trained person using this product. Individuals receiving the information must exercise their independent judgement in determining its appropriateness for a particular purpose.

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