

SAFETY DATA SHEET

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Revision 01/06/2021

Version 1.0

Section 1-Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit /
SARS-CoV-2 Surrogate Virus Neutralization Test Kit

Components: Positive Control, Negative Control, HRP conjugated RBD, HRP Dilution Buffer, Sample Dilution Buffer, TMB Solution, Stop Solution, 20x Wash Solution

Article number:

L00847, L00847-5;

L00847-A;

L00847-B;

L00847-C;

Registration number

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Relevant identified uses:

For in vitro diagnostics

Uses advised against:

No further relevant information available.

Sector of Use: SU20 Health services

Product category: PC21 Laboratory chemicals

Process category: PROC15 Use as laboratory reagent

Application of the substance / the mixture

Immunochemical reagent for detection / auxiliary reagent for in-vitro diagnosis.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Manufacturer:

Nanjing GenScript Biotech Co., Ltd.

No. 28, Yongxi Road, Jianging District

Nanjing, Jiangsu, 211100 China

Tel.: +86-25-58897288-3005

Informing department:

Department R&D Department

product@genscript.com

1.4 Emergency telephone number:

Emergency Phone: +1-732-885-9188 (service in English, 24 hours permanently accessible).

Section 2- Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008


According to Regulation (EC) No 1272/2008 components of the mixture are classified as hazardous.

Component(s)	Classification	
Positive Control, Negative Control, HRP conjugated RBD, HRP Dilution Buffer, Sample Dilution Buffer, 20x Wash Buffer	Skin Sens. 1 Aquatic Chronic 3	H317 May cause allergic skin reaction. H412 Harmful to aquatic environment.
TMB Solution	The product is classified according to CLP regulation.	
Stop Solution	The product is classified according to CLP regulation.	

2.2 Label elements


Labelling according to Regulation (EC) No 1272/2008

The components are classified and labeled in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Component(s)	Positive Control, Negative Control, HRP conjugated RBD, HRP Dilution Buffer, Sample Dilution Buffer, 20x Wash Buffer
Hazard pictograms	
Signal word	Warning
Hazard-determining components of labelling:	Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol.3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)
Hazard statements	H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long effects.
Precautionary statements	P273 Avoid release to the environment. P280 Wear protective gloves / protective clothing / eye protection P302+P352 IF ON SKIN: Wash with plenty of water. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
Additional information	Restricted to professional users

Labelling of packages where the contents do not exceed 125 ml

Component(s)	Positive Control, Negative Control, HRP conjugated RBD, HRP Dilution Buffer, Sample Dilution Buffer, 20x Wash Buffer
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Hazard pictograms	
Signal word	Warning
Hazard-determining components of labelling:	Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)
Hazard statements	H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long effects.
Precautionary statements	P273 Avoid release to the environment. P280 Wear protective gloves / protective clothing / eye protection

The components are not subject to labelling according to Regulation (EC) No. 1272/2008 (GHS/CLP).

Component(s)	TMB Solution, Stop Solution
Additional information	Safety data sheets available on request.

2.3 Other hazards Void.









PBT: Substances do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.

vPvB: Substances do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

Section 3- Composition/information on ingredients




3.2 Chemical characterization: Mixtures



3.1 Chemical characterization: substances Not applicable. Product is a mixture.

Components:	Positive Control, Negative Control, HRP conjugated RBD, HRP Diluent Buffer, Sample Diluent Buffer, 20x Wash Buffer	
Dangerous components:		
CAS: 55965-84-9 Index number: 613-167-00-5	Gemisch aus/Mixture aus 5-.Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-Isouthiazol-3-on [EG-Nr. 220-239-6] (3:1)  Acute Tox. 3, H310;  Acute Tox. 2, H310;  Acute Tox. 2, H330  Skin Corr. 1C, H314;  Eye Dam. 1, H318  Aquatic Acute 1, H400;  Aquatic Acute Chronic 1, H410  Skin Sens. 1A, H317	≥0.0025 -<0.025 %

Description: Immunochemical reagent / auxiliary reagent

Components:	TMB Solution	
Dangerous components:		
CAS:7722-84-1	Hydrogen peroxide solution	<5 %

EINECS:231-765-0	 Ox. Liq. 1, H271	
Index number:	 Skin Corr. 1A, H314	
008-003-00-9	 Acute Tox. 4, H302; Acute Tox. 4, H332	

Components		Stop Solution
Dangerous components:		
CAS: 7647-01-0	Hydrochloric acid	<3,2 %
EINECS: 231-595-7	 Skin Corr. 1B, H314	
Index number:	 STOT SE 3, H335	
017-002-00-2		

SVHC Not applicable.

Additional information For the wording of the listed H-phrases please refer to Section 16.

Section 4- First aid measures

4.1 Description of first aid measures

General information First aider: Take care of self-protection

After inhalation

Supply fresh air.

In case of symptoms call a physician

After skin contact

Instantly clean with much water and soap.

In case of symptoms call a physician.

After eye contact

Rinse eyes cautiously with water for several minutes. Remove contact lenses if present and easy to do.

Continue rinsing.

Instantly consult ophthalmologist.

After swallowing In case of symptoms call a physician.

Information for doctor

Show Safety Data Sheet.

Treatment according to symptoms

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available for these mixtures.

Danger No further relevant information available.

4.3 Indication of any intermediate medical attention and special treatment needed

No further information available.

Section 5- Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents CO₂, extinguishing powder, foam or water spray jet.

For safety reasons unsuitable extinguishing agents For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

In case of fire of large quantities:

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing/safety glasses.

Additional information

Collect contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

Section 6- Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

Advice for emergency responders: Protective equipment: see Section 8

6.2 Environmental precautions: Do not empty into drains.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Dispose of the material collected according to respective national regulations.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

Section 7- Handling and storage

7.1 Precautions for safe handling

Observe label precautions.

Open and handle container with care.

Prevent inhalation, swallowing and contact with eyes and skin.

Information about protection against explosions and fires:

The product is not flammable.

No danger of explosion.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and containers:

Store container tightly closed in a cool location.

Reseal opened containers and keep them upright to prevent any leakage.

Store at +2 °C to +8 °C

Information about storage in one common storage facility: For this mixture no further information available.

Further information about storage conditions:

Store in a locked cabinet or with access restricted to technical expert or their assistants.

Storage class See the respective national guidelines.

7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

Section 8- Exposure controls/personal protection

8.1 Control parameters

Additional information about design of technical systems: No further data; see Section 7

Components with critical values that require monitoring at the work place:	
7722-84-1 hydrogen peroxide solution	
WEL	Short-term value: 2.8 mg/m ³ , 2 ppm Long-term value: 1.4 mg/m ³ , 1 ppm
7647-01-0 hydrochloric acid	
WEL	Short-term value: 8 mg/m ³ , 5 ppm Long-term: 2 mg/m ³ , 1 ppm (gas and aerosol mists)

DNELs No further relevant information available.

PNECs No further relevant information available.

Additional information: The official lists were valid during the compilation were used as basis.

8.2 Exposure controls

Technical measures and appropriate working operation should be given over priority over the use of personal protective equipment.

See Section 7.

Personal protective equipment

General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

Wash hands during breaks and at the end of the work.

Breathing equipment: No special precautions are necessary if handled correctly.

Protection of hands:

Protective gloves (AQL 1.5).

The breakthrough times stated below base on laboratory test methods which cannot fully simulate working conditions. It

is the responsibility of the end user to choose the appropriate gloves for his application. If working with substances or

mixtures harmful in contact with skin, check the gloves beforehand for holes and fissures.

Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

Product quality must comply with standard EN 374.

Penetration time of glove material Penetration time > 120 min.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Product has not been designed for permanent contact.

For the permanent contact gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Eye protection: Safety glasses (standard EN 166).

Body protection: Protective work clothing.

Limitation and supervision of exposure into the environment Do not empty into drains.

Risk management measures Void.

Section 9- Physical and chemical properties

9.1 Information on basic physical and chemical properties

	Component			
	Positive Control Negative Control HRP conjugated RBP HRP Diluent Buffer Sample Diluent Buffer	20x Wash Solution	TMB Solution	Stop Solution
Appearance				
Form:	liquid			
Color:	yellowish	colorless	colorless	colorless
Smell:	odorless			
Odor threshold:	No information available.			
Important information on protection of health and environment, and on safety.	No further relevant information available.			
pH-value	No information available.			
Change in condition	No information available			
Melting point/ freezing point:	No information available.			
Flash point	No information available.			
Inflammability (solid, gaseous)	No information available.			
Ignition temperature	No information available.			
Decomposition temperature:	No information available.			
Self-inflammability:	No information available.			
Explosive properties	Not explosive.			
Critical values for explosion:				
Lower:	Not applicable.			
Upper:	Not applicable.			
Oxidizing properties:	No information available.			

Steam pressure:	No information available.			
Density	No information available.			
Relative density	No information available.			
Vapor density	No information available.			
Evaporation rate	No information available.			
Solubility in / Miscibility with Water:	Fully miscible.			
Viscosity:				
dynamic:	No information available.			
kinematic:	No information available.			
Solvent content:				
Organic solvents:	0.1 %	0.1 %	0.0 %	0.0 %
Water:	99.9 %	99.9 %	95 %	96.8 %
Solids content	0.0 %	0.0 %	> 0.0 %	> 0.0 %

9.2 Other information No further information available.

Section 10- Stability and reactivity

10.1 Reactivity The mixture is chemically not reactive.

10.2 Chemical stability The product is chemically stable under the indicated storage conditions

Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to the specifications.

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected when handling the product to its intended use.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: In case of fire of large quantities: See Section 5

Additional information: No further information available.

Section 11- Toxicological information

11.1 Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC₅₀ values that are relevant for classification:		
55965-84-9 Gemisch aus/Mixture of: 5-chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)		
Oral	LD ₅₀	3.5 mg/kg (rat)

Dermal	LD ₅₀	>5,000 mg/g (rat)
Inhalative	LD ₅₀ /4 h	0.33 mg/l (rat)

Specific symptoms in biological assay: No further relevant information available.

Primary irritant effect:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

after swallowing: Mucosal irritations in mouth, pharynx and oesophagus possible.

after inhalation: Irritations possible.

Respiratory or skin sensitization

May cause an allergic skin reaction.

Other information (about experimental toxicology): No further relevant information available.

Subacute to chronic toxicity: No further relevant information available.

Additional toxicological information: No further relevant information available.

Toxicokinetics, metabolism and distribution No relevant information available.

Acute effects (acute toxicity, irritation and corrosivity) No further relevant information available.

Sensitization May cause allergic reactions.

Repeated dose toxicity No further relevant information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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 exposure Based on available data, the classification criteria are not met.

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

Section 12- Ecological information

12.1 Toxicity

Aquatic Toxicity: No further information available.

12.2 Persistence and degradability No further relevant information available.

Other information: No further relevant information available.

Behavior in environmental systems:

Components: No relevant information available.

12.3 Bioaccumulative potential No relevant information available.

12.4 Mobility in soil No relevant information available.

Ecotoxicological effects:

Remark: No further relevant information available.

Additional ecological information:

General notes: Do not allow product to reach ground water, water bodies or sewage system!

12.5 Results of PBT and vPvB assessment

PBT: PBT assessment not available as chemical safety assessment not required/not conducted.

vPvB: vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects No relevant information available.

Section 13- Disposal considerations

13.1 Waste treatment methods

Product residues have to be disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

Uncleaned packagings:

Recommendation: Uncleaned packaging have to be disposed of in the same manner as the product residues.

Section 14- Transport information

14.1 UN-Number	-
ADR, ADN, IMDG, IATA	
14.2 UN proper shipping name	-
ADR, ADN, IMDG; IATA	
14.3 Transport hazard class(es)	-
ADR, ADN, IMDG; IATA Class	
14.4 Packing group	-
ADR, ADN, IMDG; IATA	
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
Transport/Additional information:	Not classified as dangerous in the meaning of transport regulations as issued in the latest version. The transport regulations are cited according to international regulations and in the form applicable in Germany (GGVSE).

Possible national deviations in other countries are not considered

UN "Model Regulation": -

Section 15- Regulatory information

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

Labelling according to Regulation (EC) No 1272/2008 See Section 2

Hazard pictograms See Section 2

Signal word See Section 2

Precautionary statements See Section 2

Chemical safety assessment A chemical safety assessment was not carried out.

Directive 2021/18/EU

Named dangerous substances – ANNEX I Contains none of the listed substances.

REGULATION (EC) No 1907/2006 ANNEX XVII Contains of restriction: 3

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment None of the ingredients is listed.

National regulations

Information about limitation of use:

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant an breast feeding mothers and workers of childbearing age in the latest version.

Water hazard class:

Component	Water hazard class
Positive Control, Negative Control, HRP conjugated RBD, HRP Dilution Buffer, Sample Dilution Buffer, 20x Wash Solution	Water hazard class 2 (Self-assessment): Hazardous for water.
TMB Solution	Water hazard class 1 (Self-assessment): Slightly hazardous for water.

Stop Solution	Water hazard class 1 (Self-assessment): slightly hazardous for water.
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15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

Section 16- Other information

The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS SDS DOES NOT CONSTITUTE A WARRENTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PUPOSE"

Relevant phrases

H271 May cause fire or explosion; strong oxidizer.; H301 Toxic if swallowed.; H302 Harmful if swallowed.; H310 Fatal in contact with skin.; H314 Causes severe skin burns and eye damage.; H317 May cause an allergic skin reaction.; H318 Causes serious eye damage.; H330 Fatal if inhaled.; H332 Harmful if inhaled.; H335 May cause respiratory irritation.; H400 Very toxic to aquatic life.; H410 Very toxic to aquatic life with long lasting effects.

Department issuing data specification sheet: R&D Department

Contact: product@genscript.com

Replaces version from: -

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road); IMDG: International Maritime Code for Dangerous Goods; IATA: International Air Transport Association; GHS: Globally Harmonised System of Classification and Labelling of Chemicals; EINECS: European Inventory of Existing Commercial Chemical Substances; ELINCS: European List of Notified Chemical Substances; CAS: Chemical Abstracts Service (division of the American Chemical Society); DNEL: Derived No-Effect Level (REACH); PNEC: Predicted No-Effect Concentration (REACH); PBT: Persistent, Bioaccumulative and Toxic; SVHC: Substances of Very High Concern; vPvB: very Persistent and very Bioaccumulative; Skin Corr. 1B: Skin corrosion/irritation – Category 1B; STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

