Material Safety Data Sheet (MSDS)

According to In Vitro Diagnostic Medical Device Regulation (EU) 2017/746

File No.: TD020-MSDS
Version: 01
Product: Strep A Rapid Test
Model: GISTA-702H

	Title	Signature	Date
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SAFETY DATA SHEET

1. INDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY UNDERTAKING

Product name	Strep A Rapid Test
Chemical description/Application	The Strep A Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Strep A antigens in human throat swab samples. It is an in-vitro diagnostic reagent intended for use as an aid in the diagnosis of Streptococcus A (Strep A) infections in patients showing typical symptoms of a local throat infection. The Strep A Rapid Test is designed for self-testing. It is not for near-patient testing. Also, it's not automated.
Supplier	Zhejiang Greylynx Biotech Co., Ltd. Floor 3/4, Building 4, No. 17 Jianxing Road, Taozhu Street Zhuji, 311800, Zhejiang, P.R. China

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2. HAZARDS IDENTIFICATION

Hazard class and label elements of the product according to Regulation (EC) No. 1272/2008 [EU-GHS/CLP]:

GHS Hazard class	Non-hazardous substance or mixture.
GHS label elements	Pictogram(s): None Pictogram(s): None
Hazard statements	Not applicable.
Other Hazards	None.
Hazard description	**Physical and chemical hazards:** Non-flammable, no special combustion and explosion characteristics. **Health hazards:** None **Environmental hazards:** None

3. COMPOSITION /INFORMATION ON INGREDIENTS

The Strep A Rapid Test is stored in a sealed aluminum foil bag with desiccant, positive control and the buffer is prefilled in a bottle. Each test kit contains the following chemicals.

Component(s)		Content, %	CAS No.	Classification
Positive control	NaCl	0.0085	7647-14-5	Not Classified
	$Na_2HPO_4 \cdot 12H_2O$	0.0308	10039-32-4	Skin Corr. 2; H315 Eye Corr. 2A; H318 Acute Tox. 4 (Inh.); H333
	$NaH_2PO_4 \cdot 2H_2O$	0.0028	13472-35-0	Skin Corr. 3; H316 Eye Corr. 2B; H320 Acute Tox. 4 (Inh.); H333
	Strep A Culture	N/A	N/A	Not Classified
	Proclin300	0.001	N/A	Acute Tox. 4 (Oral); H302 Acute Tox. 4 (Skin); H313 Skin Corr. 1B; H314 Skin sen. 1; H317 Eye Corr. 1; H318 Acute Tox. 4 (Inh.); H332 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Strep A Reagent A	Water	To 100	7732-18-5	Not Classified
	Tris	0.0121	77-86-1	Not Classified
	$NNaO_2$	6.9	7632-00-0	Oxidizing solid 3; H272 Acute Tox. 3 (Oral); H301 Aquatic Acute 1; H400
	Phenol Red	0.00004	34487-61-1	Skin Corr. 2; H315 Eye Corr. 2A; H319 STOT-SE ; H335
Strep A Reagent B	Water	To 100	7732-18-5	Not Classified
	CH_3COOH	0.857	64-19-7	Flammable liquids 3; H226 Skin Corr.1A; H314 Eye Corr. 1; H318
Test Device	GAR	0.2	N/A	Not Classified

Component(s)		Content, %	CAS No.	Classification
	Rabbit Anti-Strep A polyclonal antibodies	0.1	N/A	Not Classified
	Rabbit Anti-Strep A polyclonal antibodies	0.1	N/A	Not Classified

4. FIRST–AID MEASURES

Description of first aid measures

General advice Show this material safety data sheet to the doctor in attendance.
After receiving the first-aid measure required, consult a physician if necessary.

Skin advice Remove contaminated clothing and shoes.
Wash off with mild soap and plenty of water.
If skin irritation occurs or persists, consult a physician immediately.

Eves contact Check for and remove any contact lenses, occasionally lifting the upper and lower eyelids. Immediately flush eyes with running water, disappear until the chemical residues so far.
Provide a readily-accessible eyewash facility and quick-drench safety shower.
Do not rubbing eyes with hand.
If eye irritation occurs or persists, consult a physician immediately.

Inhalation Move exposed person to fresh air. Maintain an open airway. Keep person warm and at rest.
If breathing is irregular, provide artificial respiration or oxygen by trained personnel.
Get medical attention if adverse health effects persist or are severe.

Ingestion Wash out mouth with water. Move exposed person to fresh air. Keep person warm and at rest.
If material has been swallowed and the exposed person is conscious, give small quantities of water to drink.
Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel.
If vomiting occurs, the head should be kept low so that vomit does not enter the lungs.
Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person.

Most important acute and delayed symptoms/effects

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

Immediate/special treatment

Continue with first aid measures. Treat symptomatically and supportively.
Symptoms may be delayed.

5. FIRE FIGHTING MEASURES

Extinguishing agents

Suitable extinguishing agents

Use dry sand, dry chemical or CO_2 foam extinguishing.
Water spray can be used to cool fire exposed containers/materials.
Use extinguishing media most appropriate for the surrounding fire.

Unsuitable extinguishing agents

Do not uses a solid water stream as it may scatter or spread fire.

Special hazards

If this product is involved in a fire, the following can be released: Carbon oxides, sodium oxides, etc.

Fire precautions and measures

Firefighters must wear self-contained breathing apparatus, wear full body fire suit, fire extinguishing in the upwind.
As far as possible will be transferred to empty containers from the scene.
Keep the fire water spray containers cooling, until the end of fire.
If the containers in the fire ground have been color, must be evacuated immediately.
Isolated accident scene, prohibit access.
Receiving and processing of fire, to prevent environmental pollution.

6. ACCIDENTAL RELEASE MEASURES

Personal precaution

No action shall be taken involving any personal risk or without suitable training.
Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering.
Do not touch or walk through spilt material, avoid slipping.

Avoid breathing steam.
Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate.
Put on appropriate personal protective equipment (see section 8).

Environmental precautions Prevent further leakage or spillage if safe to do so. Discharge into the environment must be avoided.

Methods for cleaning up Small spill: Stop leak if without risk. Move containers from spill area. Wash the leakage with plenty of water.
Large spill: Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.q. sand, earth, vermiculite or diatomaceous earth.
Solid: Pick up and arrange disposal without creating dust. Collect mechanically. Keep in suitable, closed containers for disposal.
Contaminated absorbent material may pose the same hazard as the spilt product.
Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

7. HANDLING AND STORAGE

Handling Put on appropriate personal protective equipment (see section 8).
Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed.
Workers should wash hands and face before eating, drinking and smoking. Avoid contact eyes. Avoid breathing steam.
Provide suitable exhaust equipment. Operate in a well-ventilated place.
Normal measures for preventive fire protection. Keep away from heat/sparks/open flames/hot surfaces.
Observe good housekeeping procedures and hygiene practices
Handling carefully to prevent damage the packaging and container.
Wash thoroughly after handling.
Persons with a history of skin sensitization problems should not be employed in any process in which this product is used.
Equipped with corresponding varieties and number of fire equipment and spill contingency processing equipment.

Storage	Store the test kit in a cool, dry place between 2-30 °C. Keep container tightly closed. Keep away from sparks, open flames and high temperatures, away from incompatible materials (see section 10). Keep container tightly closed and sealed until ready for use. Equipped with corresponding varieties and number of fire equipment and spill contingency processing equipment. Keep out of reach children and pets.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits	There is no known exposure limits prescribed by the state.
Engineering controls	Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.
Personal protection	
General requirements	
Respiratory protection	If exposure limits are exceeded or if irritation or other symptoms are experienced, use multi-function respirator.
Eye protection	Wear safety glasses when there is a potential for eye contact.
Skin and body protection	Wear suitable protective clothing and boots.
Hand protection	Wear protective gloves. Check protective gloves prior to each use for their proper condition. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

9. PHYSICAL-CHEMICAL PROPERTIES

Appearance	The test kit contains a test cassette that is a plastic card with a sample hole and reaction window, and the clear buffer. The plastic card is white, the buffer is clear and colorless.
Odor	Odorless

Odor threshold	No date
Melting point (℃)	No date
Boiling point (℃)	No date
Melting Point (℃)	No date
Flash point (℃)	No date
Evaporation rate	No date
Steam pressure (20℃)	No date
Relative density	No date
Partition coefficient n-octanol/water	No date
Decomposition (℃)	No date
Auto ignition temperature(℃)	No date
pH value	No date
Explosion limit [% (v/v)]	No date
Relative vapor density	No date
Solubility	Test device: Insoluble in water; Buffer: Soluble in water
Flammability (solid, gas)	Test device: Non-flammable; Buffer: Not applicable
Oxidizing properties	The substance does not belong to oxidizing substances

10. STABILITY AND REACTIVITY

Stability	The product is chemically stable.
Reactivity	Stable under recommended storage and handling conditions.
Incompatible materials strong bases.	Strong oxidizing agents, strong acids and
Conditions to avoid	In contrast to the nature of the material, direct sunlight, high temperature and open fire.
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Component(s)	CAS No.	LD_{50}(Oral)	LD_{50}(Dermal)	LD_{50}(Inhalation)
$Na_2HPO_4 \cdot 12H_20$	10039-32-4	Mouse: 430mg/kg	No data	No data
Proclin300	/	Rat：53mg/kg Mouse: 60mg/kg	No data	No data

Component(s)	CAS No.	LD_{50}(Oral)	LD_{50}(Dermal)	LD_{50}(Inhalation)
$NNaO_2$	7632-00-0	Rat：186mg/kg	No data	No data

Respiratory Sensitization These products are not known to cause human respiratory sensitization.

Skin Sensitization These products are not known to cause skin sensitization.

Germ cell mutagenicity According to the existing data, the product is not classified.

Carcinogenicity No classification data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.

Reproductive toxicity According to the existing data, the product is not classified.

Specific target organ toxicity According to the existing data, the product is not classified.

Aspiration hazard According to the existing data, the product is not classified.

Additional reproductive toxicity hazards According to the existing data, the product is not classified.

12. ECOLOGICAL INFORMATION

Aquatic toxicity According to the existing data, the product is not classified.

Persistence and degradability The products are usually with natural biodegradable.

Bio accumulative potential The potential for bioaccumulation of this material in aquatic organisms is low.

Mobility in soil Will penetrate into the soil, will be dissolved in the soil material.

Results of PBT and vPvB assessment

Component(s)	CAS No.	Results of PBT and vPvB assessment (According to (EC) No. 1907/2006)
Water	7732-18-5	Not belong to PBT/vPvB
$NNaO_2$	7632-00-0	Not belong to PBT/vPvB
Proclin300	55965-84-9	Not belong to PBT/vPvB

Component(s)	CAS No.	Results of PBT and vPvB assessment (According to (EC) No. 1907/2006)
$Na_2HPO_4 \cdot 12H_2O$	10039-32-4	Not belong to PBT/vPvB
$NaH_2PO_4 \cdot 2H_2O$	13472-35-0	Not belong to PBT/vPvB
Phenol Red	34487-61-1	Not belong to PBT/vPvB

13. DISPOSAL CONSIDERATIONS

Waste disposal

Residual waste Before disposal should refer to the relevant national and local laws and regulation. The generation of waste should be avoided or minimized wherever possible.
You may be able to dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber system or transfer to a suitable container and arrange for collection bv specialized disposal company if recycling is not feasible.

Contaminated packaging The generation of waste should be avoided or minimized wherever possible.
Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Disposal considerations Dispose of container and unused contents in accordance with national and local relevant regulations laws.

14. TRANSPORT INFORMATION

Transport rules According to IATA DGR 61st Edition for transportation, IMO International Maritime Dangerous Goods Code (Amendment 39-18), European Agreement Concerning the International Carriage of Dangerous Goods by Road. The products are not subiect to IATA DGR, IMDG and ADR/RID.

Road transport (UN-ADR)

UN number Not regulated

UN proper shipping name Not regulated

Transport hazard Class Main: Not regulated

Sub risk: None

Packaging group Not regulated

Special provisions None

Hazard code None

Air transport (ICAO-IATA/DGR)

UN number Not regulated

UN proper shipping name Not regulated

Transport hazard Class Main: Not regulated

Sub risk: None

Packaging group Not regulated

Special provisions None

ERG code None

SEA transport (IMDG-CODE)

UN number Not regulated

UN proper shipping name Not regulated

Transport hazard Class Main: Not regulated

Sub risk: None

Packaging group Not regulated

Special provisions None

ERG code None

15. REGULATORY INFORMATION

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

Regulatory information: Reference to the local, national, US, EU, CA and international regulations.

CAS No.	TSCA	IECSC	EINECS/ELINCS/NLP	DSL/NDSL
7732-18-5	Listed	Listed	Listed	Listed DSL
7632-00-0	Listed	Listed	Listed	Listed DSL
55965-84-9	Unlisted	Listed	Unlisted	Listed DSL
10039-32-4	Unlisted	Listed	Unlisted	Unlisted

CAS No.	TSCA	IECSC	EINECS/ELINCS/NLP	DSL/NDSL
13472-35-0	Unlisted	Listed	Unlisted	Unlisted
34487-61-1	Listed	Listed	Listed	Listed DSL

16. OTHER INFORMATION

Reference IARC
OECD: The Global Portal to Information on Chemical Substances
U.S. Department of Transportation: ERG
Germany GESTIS-database on hazard substance
CAMEO Chemicals
NLM: ChemIDplus
EPA: Integrated Risk Information System
IPCS: The International Chemical Safety Cards (ICSC)

Disclaimer The above information is believed to be correct but we cannot guarantee the absolute universality and accuracy and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.