SECTION 1: Identification

1.1. Identification

Product form: Article

Product name: Strep A Rapid Test

Product code: P2019C01, P2019C02, P2019C05, P2019C10, P2019C20

1.2. Recommended use and restrictions on use

Recommended use: For in Vitro Diagnosis Use

Restrictions on use: For professional laboratory and self-testing use

1.3. Supplier

Manufacturer

GenSure Biotech Inc.

Address: 5F, No. 5, Lane 396, Luzhouhuan Rd., Minhang District, 201114 Shanghai, China.

E-Mail: info@gensurebio.com

1.4. Environmental precautions

Emergency telephone number: +86-21-68068136 (Shanghai)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified (CLP).

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

According to EC directives or the corresponding national regulations there is no labeling obligation for this product.

2.3. Other hazards

No additional information available.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Chemical name	CAS-No.	Concentration
Extraction buffer	Tris	77-86-1	0.05 mol/L
	Sodium chloride	7647-14-5	0.15 mol/L
	NP-40	9016-45-9	1%
	Proclin 300	-	0.04%

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II.

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing

First-aid measures after skin contact: Wash skin with plenty of water.

First-aid measures after eye contact: Rinse eyes with water as a precaution.

First-aid measures after ingestion: Call a poison center or a doctor if you feel unwell.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray. Dry powder. Foam.

5.2. Specific hazards arising from the chemical

No additional information available

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures: Ventilate spillage area

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection"

6.2. Environmental precautions

Environmental precautions: Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Mechanically recover the product.

Other information: Dispose of materials or solid residues at an authorized site

Reference to other sections: Ensure good ventilation of the work stationl.

Environmental exposure controls: For further information refer to section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a well-ventilated place. Keep cool.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls: Ensure good ventilation of the work station.

Environmental exposure controls: Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Materials for protective clothing: Lab coat

Eye protection: Safety glasses

Skin and body protection: Wear suitable protective clothing

Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):

Other information: Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Appearance:	In vitro diagnostic medical test kit.
Colour:	No data available.
Odour:	No data available.
Odour threshold:	No data available.
pH:	All reagents in this kit are neutral.
Melting point:	No data available.
Freezing point:	Not applicable.
Boiling point:	No data available.
Flash point:	Not applicable.
Relative evaporation rate (butylacetate=1):	No data available.
Flammability (solid, gas):	Non flammable.
Vapour pressure:	No data available.
Relative vapour density at 20 °C:	No data available.
Relative density:	No data available.
Solubility:	No data available.
Partition coefficient n-octanol/water (Log Pow):	No data available.
Auto-ignition temperature:	Not applicable.
Decomposition temperature:	No data available.
Viscosity, kinematic:	No data available.
Viscosity, dynamic:	No data available.
Explosive limits:	Not applicable.
Explosive properties:	No data available.
Oxidising properties:	No data available.

9.2. Other information

No additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity (oral):	Not classified
Acute toxicity (dermal):	Not classified
Acute toxicity (inhalation):	Not classified
Skin corrosion/irritation:	Not classified
Serious eye damage/irritation:	Not classified
Respiratory or skin sensitisation:	Not classified
Germ cell mutagenicity:	Not classified
Reproductive toxicity:	Not classified
STOT-single exposure:	Not classified
STOT-repeated exposure:	Not classified
Aspiration hazard:	Not classified
Viscosity, kinematic:	No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

No additional information available.

12.3. Bioaccumulative potential

No additional information available.

12.4. Mobility in soil

No additional information available.

12.5. Other adverse effects

No additional information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Regional legislation (waste):	Disposal must be done according to official regulations.
Waste treatment methods:	Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations:	Disposal must be done according to official regulations.
Ecology - waste materials:	Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT):	Not regulated.
Transport by sea:	Not regulated.
Air transport:	Not regulated.

SECTION 15: Regulatory information

15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV).

This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable.

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Does not apply.

International Inventories

Not determined.

TSCA	-
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

Note:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances

SECTION 16: Other information

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Issue Date: 8-Jul-2024

Revision Date: 8-Jul-2024

Revision Note: New format

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet