SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade Name:	**Multi-Drug Rapid Test Cup(Oral Fluid)**
Catalog Number:	**DSD-8X7**

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

Rapid Test kit for In vitro Diagnostic. Professional Use Only.

1.3 Details of the supplier of the safety data sheet

Manufacturer:	Hangzhou Alltest Biotech Co., Ltd
Address:	No 550, Yinhai Street, Hangzhou Economic and Technological Development Area, Zhejiang Province, China
Phone number:	Phone number is available during office hours (8 am-5 pm Mon-Fri) as follows: +86-0571-56267850
Fax number:	+86-0571-56267856
E-Mail Contact Person:	Yan.Zhang@alltests.com.cn

1.4 Emergency Telephone Number

Telephone No.: (+352) 8002 5500
Other comments: Information available 24/7 in French, Dutch and English.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

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

Not Classified

2.1.2 Additional information

For full text of hazard and EU hazard statements: see SECTION 16.

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008 (CLP)

Hazard picograms and Signal word:	*No*
Hazardous components for labeling:	*No*
Hazard statements:	*No*
Precautionary statements:	*No*
Supplemental Hazard information (EU):	*No*

2.3 Other hazards

At this concentration (0.02%) of Proclin 300, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested . ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317]

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This product is a mixture.

3.2 Mixtures

Hazardous ingredients	CAS No.	EC No.	Index No.	REACH Registration No.	Classification according to Regulation (EC) No. 1272/2008 (CLP)	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9	N/A	613-167-00-5	N/A	Acute Tox. 3: H301 Acute Tox. 2: H310 Skin Corr. 1C: H314 Eye Dam. 1: H318 Skin Sens. 1A: H317 Acute Tox. 2: H330 Aquatic Acute 1: H400 Aquatic Chronic 1: H410	<0.001 %

Specific concentration limits, M-factors, Acute Toxicity Estimates (ATEs) and generic cut-off values of hazard substance:

Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1):

- Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1%
- Specific concentration limits, M-factors, Acute Toxicity Estimates (ATEs) according to Table 3.1 Annex VI:

Skin Corr. 1C; H314: C ≥ 0.6 %

Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 %

Eye Dam. 1; H318: C ≥ 0.6 %

Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 %

Skin Sens. 1A; H317: C ≥ 0.0015 %

M(Acute) = 100

M(Chronic)=100

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

General notes	Due to lack of classification, negative symptoms or effects are not expected where the product is used as foreseen.
After inhalation	No specific first aid measures noted. If you feel unwell, seek medical advice.
After skin contact	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact: May cause skin irritation.
Symptoms/effects after eye contact: Liquid splashes in the eye may cause irritation.
Symptoms/effects after ingestion: Ingestion may cause nausea and vomiting.

4.3 Indication of any immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	The common fire extinguish media can be used
Unsuitable extinguishing media:	There are no unsuitable extinguishing media expected

5.2 Special hazards arising from the substance or mixture

No specific hazardous decomposition products noted.

5.3 Advice for firefighters

1. Wear usual Firefighter Personal Protective Equipment.
2. Use dry-chemical fire extinguisher.
3. Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
4. Protection during firefighting: Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

(a) General measures: Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) - see Section 8.
(b) Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.

6.2 Environmental precautions

Keep away from drains surface and ground water. Dispose as infections material.

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:	Kept in the primary package and secondary package before use.
6.3.2 For cleaning up:	Clean up with broom
6.3.3 Other information:	No data applicable

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Recommendations
Wear appropriate personal protective equipment - see Section 8. Used device to be handled as infectious.
7.1.2 General hygiene measures:
Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.
7.2 Conditions for safe storage, including any incompatibilities
Information about storage conditions: Note the storage conditions on product packaging. **Requirements for storage rooms and containers:** Store 2-30℃. Keep away from sunlight and Keep dry.
7.3 Specific end use(s)
A rapid test for the qualitative detection of multiple drugs and drug metabolites in human oral fluid. For professional in vitro diagnostic use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters	
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.	
8.2 Exposure controls	
8.2.1 Appropriate engineering controls	
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.	
8.2.2 Personal protective equipment	
General protective and hygienic measures:	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
Respiratory protection	Not required
Protective gloves	Disposable gloves
Material of gloves	Latex/natural rubber
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the instruction for use. Common medical gloves are acceptable.
Eye Protection	Safety glasses
Body protection	Lab personal protective equipment (PPE)
8.2.3 Environmental exposure controls	
There are no special precautions and measures. See section 6 and 7!	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	
Physical State:	Solid
Colour:	White appearance and some content of the test strip is colored
Odour:	Odourless
Melting point/freezing point	Not applicable to mixture.
Boiling point:	Not applicable to mixture.
Flammability:	No data applicable
Lower and upper explosion limit	There is no substances in the kit could lead to the danger of explosion
Flash point:	No data applicable
Auto-ignition temperature:	Product is not known to be self-igniting
Decomposition temperature	No data applicable
pH-value at 20°C:	Not established
Kinematic viscosity	Not applicable to mixture.
Solubility	No data applicable
Partition coefficient n-octanol/water (log value)	Not applicable to mixture.
Vapour pressure:	No data applicable
Density and/or relative density	No data applicable
Relative vapour density	Not applicable to solids.
Particle characteristics	No data applicable
Solubility in water:	Not determined
9.2 Other safety information:	
No data applicable	

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity
The product is stable in accordance with the recommended storage conditions.
10.2 Chemical stability

Stable under normal conditions.
10.3 Possibility of hazardous reactions
There are no known hazardous reactions under normal conditions of storage and use.
10.4 Conditions to avoid
No known conditions.
10.5 Incompatible materials
No
10.6 Hazardous decomposition products
No

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No. 1272/2008	
Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
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.
Respiratory or skin sensitisation:	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
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.
Other Information	Based on available data, the classification criteria are not met.
11.2 Information on other hazards	
11.2.1 Endocrine disrupting properties	
Not applicable	
11.2.2 Other information	
No data applicable	

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
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
12.6 Endocrine disrupting properties
This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.
12.7 Other adverse effects
No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Do not discharge into drains or the environment. Used device to be handled as infectious. Can be disposed or incinerated according to local regulations. Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue:	18 01 03 wastes whose collection and disposable is subject to special requirements in order to prevent infection.

Packaging:	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further informations.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID number

Not applicable.

14.2 UN proper shipping name

ADR/RID: Not applicable.

IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packing group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ yes / ☑ no
Marine Pollutant : ☐ yes / ☑ no

14.6 Special precautions for user

See sections 6-8

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

EU regulations:	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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC REGULATION (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

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H301	Toxic if swallowed
H310	Fatal in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H317	May cause an allergic skin reaction
H330	Fatal if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Indication of changes

2022-12-13	Update according to *COMMISION REGULATION(EU) 2020/878 of 18 June 2020* and *Guidance on the compilation of safety data sheets Version 4.0*.

General information

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].
The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user`s responsibility to determine the suitability of the information for their particular purposes.

Document Approval Record

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Hangzhou AllTest Biotech Co., Ltd - Multi-Drug Rapid Test Cup (Oral Fluid) - SDS
Author: Jason Lo

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