



MSDS-0044/02
2024.05.08

MATERIAL SAFETY DATA SHEET

Oral Fluid Drug Test

According to REACH Regulation (EC) No. 1907/2006, Annex II

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: **Oral Fluid Drug Test**

Reference No.:

CB Name	Healgen Code
HE-ORAL-18104IPR	CB-HE-SWI-18104
HE-ORAL-6124IPR	CB-HE-SWI-6124
HE-ORAL-5144AIPR	CB-HE-SWI-5144A
HE-ORAL-253IPR	CB-HE-SWI-253
HE-ORAL-264IPR	CB-HE-SWI-264
HE-ORAL-19104IPR	CB-HE-SWI-19104

unique formula identifier (UFI):/

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

Description of the substance/mixture: For professional use only.

1.3 Details of the supplier of the safety data sheet

Supplier: ZheJiang Orient Gene Biotech Co.,Ltd.

Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300,Huzhou,Zhejiang,China.

Tel: [+86-572-5226111](tel:+86-572-5226111)

Fax: +86-572-5226222

Web: <http://www.orientgene.com>

P.C.: 313300

E-mail: sales@orientgene.com

1.4 Emergency telephone number

Emergency telephone: +86-572-5226111

2. Hazards identification

2.1 Classification of the substance or mixture:

Substance or mixture not classified as dangerous according to Directive (EC) No. 1272/2008

2.2 Label elements:

hazard pictogram(s):



GHS07

signal word(s): Warning

hazard statement(s): H302 Harmful if swallowed.

precautionary statement(s):

P264 Wash thoroughly after handling.



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P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth

P501 Dispose of contents/container in accordance with local/regional/national/international regulations

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable

PvB: Not applicable

Determination of endocrine-disrupting properties : Not applicable

3. Composition/information on ingredients

In vitro diagnostics medical device. Test strip impregnated with dried chemical / biochemical reagents.

Components:

Component	CAS No.	EINECS No.	Classification	Concentration
Chloroauric acid	16903-35-8	240-948-4	Not specified in 1272/2008	N/A
Polyvinylpyrrolidone	9003-39-8	N/A	Not specified in 1272/2008	N/A
NaH ₂ PO ₄ ·2H ₂ O	13472-35-0	231-449-2	Not specified in 1272/2008	N/A
Sodium citrate tribasic dihydrate	6132-04-3	200-675-3	Not specified in 1272/2008	N/A
Na ₂ HPO ₄ ·12H ₂ O	7558-79-4	231-448-7	Not specified in 1272/2008	N/A
Tris	77-86-1	201-064-4	Not specified in 1272/2008	N/A

4. First aid measures

4.1 Description of first aid measures

General Advice:

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip

Advice after skin contact:

Wash with soap and water and rinse thoroughly

Advice After eye contact:

Rinse opened eye for several minutes under running water.

Advice After ingestion:

If desiccant or other components are swallowed seek medical attention.



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4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire-extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Not required.

6.2 Environmental precautions

Avoid release to the environment.

Do not allow to enter sewers/ surface or ground water

6.3 Methods and material for containment and cleaning up

Dispose contaminated material as waste according to section 13.

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 disposal information

7. Handling and storage

7.1 Precautions for safe handling

For the general occupational hygienic measures refer to Section 8.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: No special requirements.



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Information about storage in one common storage facility: Store away from foodstuffs.

Further information about storage conditions: None

Store in the original container at 2-30°C.

7.3 Specific end use(s)

No further relevant information available.

8. Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values:

The product does not contain any relevant quantities of materials with limit values that have to be monitored in the workplace.

8.2 Exposure controls

Based on the composition shown in Section 3, the following measures are suggested for occupational safety measure.

Appropriate engineering controls:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

See Section 7 for information about design of technical facilities.

Individual protection measures, such as personal protective equipment

Respiratory protection: Not required.

Hand protection:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.



protective gloves

Material of gloves:

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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.



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Eyeface protection: Goggles recommended during refilling

Body protection: Protective work clothing

Thermal hazards: Not required for normal conditions of use

Environmental exposure controls:

Control measures must be made in accordance with Community environmental protection legislation.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: The device is an article containing solid components.

Colour: The plastic card is white.

Odour: Odourless

Melting point/freezing point: Not applicable

Boiling point or initial boiling point and boiling range: Not applicable

Flammability: Not applicable

Lower and upper explosion limit: Non explosive

Flash point: Not applicable

Auto-ignition temperature: Not applicable

Decomposition temperature: Not applicable

pH: Not applicable

Kinematic viscosity: Not applicable

Solubility: Test device-Insoluble in water

Partition coefficient n-octanol/water (log value): Not applicable

Vapour pressure: Not applicable

Density and/or relative density: Not applicable

Relative vapour density: Not applicable

Particle characteristics: Not applicable

9.2 Other information

Not applicable

10. Stability and reactivity

10.1 Reactivity

Stable under recommended storage and handling conditions.

10.2 Chemical stability

No further relevant information available..

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

No further relevant information available.



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10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

11. Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

acute toxicity: Harmful if swallowed.

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

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

11.2 Information on other hazards

Endocrine disrupting properties: None of the ingredients is listed.

Other information: Not applicable

12. Ecological information

12.1 Toxicity

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

No further relevant information available.

13. Disposal considerations

13.1 Waste treatment methods



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Recommendation:

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14. Transport information

14.1 UN number or ID number

Not applicable

14.2 UN proper shipping name

Not applicable

14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable.

14.5 Environmental hazards

No.

14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

14.8 Transport/Additional information:

Not applicable

15. Regulatory information

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I: None of the ingredients is listed.

Seveso category: Not applicable

Qualifying quantity (tonnes) for the application of lower-tier requirements: Not applicable

Qualifying quantity (tonnes) for the application of upper-tier requirements: Not applicable

REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)

None of the ingredients is listed.

Regulation (EU) No 649/2012

None of the ingredients is listed.

REGULATION (EU) 2019/1148



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Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer -ANNEX I (Ozonedepleting potential)

None of the ingredients is listed.

Other regulations, limitations and prohibitive regulations

SVHC Candidate List of REACH Regulation Annex XIV Authorisation (17/1/2023)

None of the ingredients is listed.

REACH Regulation Annex XVII Restriction (13/12/2021)

See Section 16 for information about restriction of use.

None of the ingredients is listed.

REACH Regulation Annex XIV Authorisation List (8/4/2022)

None of the ingredients is listed.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information

Recommended restriction of use

Not applicable

Relevant hazard statements

H272 May intensify fire; oxidiser.

H301 Toxic if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

The contents and format of this SDS are in accordance with Regulation (EC) No 1907/2006, 1272/2008 and Regulation (EU) No 2020/878.

DISCLAIMER OF LIABILITY



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