



Guangzhou Wondfo Biotech Co., Ltd.

Add: No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China

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E-mail: sales@wondfo.com.cn customerservice@wondfo.com.cn

Website: www.wondfo.com.cn

Safety Data Sheet

1. Identification

Product Name:

iSCREEN™ Urine Test Dx Drug Screen Dip Card (Buprenorphine (BUP))

Recommended Use of the Chemical and restrictions on use:

In-vitro diagnostic medical device

Manufacturer Identification:

Guangzhou Wondfo Biotech Co., Ltd.

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Guangzhou, Guangdong, P.R. China 510663

Telephone: 0086-20-32296083

Emergency Information: sales@wondfo.com.cn

2. Hazards Identification

Information Pertaining to Particular Dangers for Man and Environment:

The preparation is not classified as dangerous according to Directive 1272/2008/EC.

Classification System:

The classification is in line with current EC (European Community)-directives. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

3. Composition/Information on Ingredients

Description:

In-vitro diagnostic medical device. Test strip impregnated with chemical/ biochemical reagents.

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Sodium azide	26628-22-8	247-852-1	T+; R28 Acute Tox. 2 N; R50-53 Aquatic Acute 1 Aquatic Chronic 1 EUH032	0.01%

4. First Aid Measure

General Information:



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

- **Skin Contact:** Remove from source of exposure. Wash affected area with soap and water. If signs of infection occur, seek medical attention.
- **Eye Contact:** Remove from source of exposure, immediately flush skin with cool water. Obtain medical attention if needed or if irritation or other symptoms develop.
- **Ingestion:** If irritation or signs of toxicity occur, seek medical attention.

Indication of immediate medical attention and special treatment needed, if necessary.

Most importance: Under normal conditions of intended, this product is not expected to be health risk.

5. Fire-fighting Measures

Extinguishing Media:

Use water, powder or carbon dioxide spray. Fight larger fires with water spray or chemical foam.

Special hazards caused by the substance, its products of combustion or resulting gases:

In case of fire, the following can be released: Hazardous fumes and vapors, Carbon oxides (CO_x), Nitrogen oxides (NO_x).

Protective equipment:

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

Additional information:

The device contains combustible materials.

6. Accidental Release Measures

General Information: Use proper personal protective equipment to clean up.

Person-related safety precautions:

Clean up and wash hands with water.

Measures for environmental protection:

Avoid release to the environment.

Measures for cleaning/collecting:

Collect material and dispose of as waste according to Section 13.

7. Handling and Storage

Precautions for safe handling:

- Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children.
- Wash hands before breaks and after work.
- Clean work areas with hypochlorite or other disinfecting agent.

Storage:

Stored in 4 °C ~ 30 °C in the sealed pouch, do not freeze.



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8. Exposure Controls/Personal Protection

Ingredients with limit values that require monitoring in the workplace:

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

Personal Protective Equipment (PPE):

Breathing Protection: Not necessary, if room is well-ventilated.

Eye Protection: Wear safety glasses if necessary.

Skin Protection: Wear protective clothing or gloves if necessary.

9. Physical and Chemical Properties

General Information:

The product is an article containing solid components.

Appearance: Laminated test strips, which may be housed in a plastic holder

Odor: None.

Odor threshold: Not applicable.

pH: Not available.

Melting point/freezing point: Not applicable.

Initial boiling point and boiling range: Not applicable.

Flash point: Not applicable.

Evaporation rate: Not applicable.

Flammability (solid, gas): Will burn if involved in fire.

Upper/lower flammability or explosive limits: Not applicable.

Vapor pressure: Not applicable.

Vapor density: Not applicable.

Relative density: Not applicable.

Solubility (ies): Not applicable.

Partition coefficient: n-octanol/water: Not applicable.

Auto-ignition temperature: Not applicable.

Decomposition temperature: Not applicable.

Viscosity: Not applicable.

10. Stability and Reactivity

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

Chemical stability: Stable under ordinary conditions of use and storage. See Section 7.

Possibility of hazardous reactions: None under the normal condition.

Conditions to avoid (e.g., static discharge, shock, or vibration): Keep away from direct



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sunlight, moisture and heat; Don't freeze.

Incompatible materials: None.

Hazardous decomposition products: None.

11. Toxicological Information

Acute Toxicity: Quantitative data on the toxic effects of this product is not available.

This product is used in vitro. No sensitizing effect known.

12. Ecological Information

Ecotoxicity: The product is not classified as environmentally hazardous.

Persistence and degradability: No data is available.

Bioaccumulative potential: No data is available.

Mobility in soil: No data is available.

Other adverse effects: No other adverse environmental effects.

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed contains at licensed waste disposal site.

Local disposal regulations: Dispose in accordance with all applicable regulations.

Waste from residues/unused products: Dispose of in accordance with local regulations. Empty contains or liners may retain some product residues. The material and its container must be disposed of in a safe manner.

14. Transport Information

Land Transport ADR/RID (Cross-Border):Not restricted

Air Transport ICAO-TI and IATA-DGR: The substance is not subject to IATA DGR 58TH, 2017.Not restricted in IATA DGR.

15. Regulatory Information

OSHA: None of the ingredients is listed.

EPA: None of the ingredients is listed.

Californian Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity: None of the ingredients is listed.

SARA

Section 355 (extremely hazardous substances): Sodium azide (trace).



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Section 313 (specific toxic chemical listings): Sodium azide (trace).

16. Additional Information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Rel.: 21/07/2023