

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_尿有形清洗液_说明书_A类		
库存编码	1075742	版本号	20230712
成品尺寸	140×190mm	单位	mm
印刷色	单色	允差	±2mm
材质	80g胶版纸		
备注			
设计			
审核			
批准			



Urine Sediment Analyzer Detergent

Instructions

[Product Name] Urine Sediment Analyzer Detergent

[Basic UDI-DI] 69257945W0101060299R0QZ

[Package Specification] 50mL, 300mL, 500mL, 4x500mL

[Intended Use]

It is used for cleaning the pipeline and flow cell of Urine Sediment Analyzer, FUS Series Urinalysis Hybrid and MUS Urinalysis System.

[Test Principle]

Sodium hypochlorite has a very high oxidation potential, which can quickly oxidize and decompose grease molecules and macromolecular organics, causing them to lose adhesion and achieve the effect of cleaning.

[Main Components] 0.5% sodium hypochlorite

[Storage Conditions]

Stored at 2-30°C, protected from sunlight and in seal.

[Shelf Life]

The shelf life is 12 months if stored at 2-30°C and in seal. The reagent can be stable for 30 days after being opened if stored at 2-30°C.

[Date of Manufacture & Expiry Date] See the label.

[Applicable Instrument]

DIRUI FUS Series Urinalysis Hybrid, MUS Series Urinalysis System, FUS Series Urine Sediment Analyzer.

[Test Method]

Refer to the applicable user manual of instrument.

[Product Performance Indices]

1. Appearance: colorless or light yellow liquid without sediments, particles or floccules
2. Loading volume: no lower than the nominal value
3. pH value: at (25±1)°C, pH is 12.10±0.50
4. Between-batch difference: ΔpH≤0.50

[Warnings and Precautions]

1. The product is only for in vitro diagnosis and professional use.
2. Avoid contact with eyes, skin and clothes. If you accidentally come into contact with the skin or clothes, please wash the contact area with water immediately. If it gets into eyes accidentally, rinse immediately with plenty of water and seek medical attention. If the reagent is swallowed accidentally, seek medical attention immediately.
3. Avoid high temperature and direct sunlight.
4. Please affix the hazard labels on the product packaging in accordance with European Community regulations.

R31: contact with acid releases toxic gas

R36/38: irritating to eyes and skin

S50: do not mix with acidic solutions

S24/25: prevent contact with skin and eyes

5. Operators should comply with the laboratory safety operation regulation and dispose of them according to the local medical waste, infectious waste, industrial waste regulations, etc.

6. If any adverse events occur during use, please report to the competent authority of the Member State where the manufacturer is located.

Safety precautions:

Hazard Pictograms: No hazard pictogram is used.

Signal Word(S): No signal word is used.

Hazard Statement: Not applicable.

Precautionary statement: Not applicable.

For information about the safety technical manual, contact your local supplier or customer service representative.

[References]

CN 111808684 A A Cleaning Solution Suitable for Urine Analyzer or Secretion Analyzer and Its Application

[Symbol Explanation]

Please read Instructions	Storage temperature	Manufacturer
Catalogue number	Lot No.	Expiry date
Authorized representative	In vitro diagnostic reagent	County of manufacture
European in Vitro Diagnostic Medical Device Regulation(EU) 2017/746(IVDR)	R31 -36/38 550-24/25	Danger level

[Instructions Approved & Modified Date] 2023-07



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