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Hygienic requirements for alcohol-based disinfectant

醇类消毒剂卫生要求

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Hygienic requirements for alcohol-based disinfectant

1 Scope

This Standard specifies the raw material requirements, technical requirements, application scope, use method, packaging, transportation and storage, symbols, labels and instructions, and inspection methods of alcohol-based disinfectants.

This Standard applies to alcohol-containing disinfectants made with ethanol and/or iso(n-)propanol as germicidal ingredient, and disinfectants in which ethanol and/or iso(n-)propanol are compatible with surfactants and skin care ingredients.

This Standard does not apply to disinfectants that are compounded with ethanol or iso(n-)propanol and other germicidal ingredients, and disinfectants that use ethanol or iso(n-)propanol as solvents.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB/T 27949 Hygienic requirements for medical items disinfection

GB 27950 General requirements for hand disinfectant

GB 27951 Hygiene requirements for skin disinfectant

GB 27952 General requirements for ordinary objects surface disinfectant

GB 31640 National Food Safety Standard - Edible Alcohol

GB/T 38499 Evaluation method for stability of disinfectant

WS 310.2 Central sterile supply department (CSSD) - Part 2: Standard for operating procedure of cleaning, disinfection and sterilization

WS/T 535 Rapid detection methods on site for disinfectant used in medical and health institutions

5 Technical requirements

5.1 Physical and chemical indicators

5.1.1 pH value

The pH value shall comply with the provisions of product quality standards.

5.1.2 Active ingredient content

5.1.2.1 Ethanol disinfectant

The ethanol content shall not be less than 60 % (volume fraction) or 52 % (mass fraction); ± 10 % of the active ingredient content shall comply with the labeling amount.

5.1.2.2 iso(n-)propanol disinfectant

The iso(n-)propanol content shall not be less than 60 % (volume fraction) or 50 % (mass fraction); ± 10 % of the active ingredient content shall comply with the labeling amount.

5.1.2.3 Compound alcohol disinfectant

The total content of compound alcohol shall not be less than 60 % (volume fraction) or 50 % (mass fraction); ± 10 % of the active ingredient content shall comply with the labeling amount.

5.1.3 Stability

The product validity period shall be ≥ 12 months.

5.2 Microorganisms killing indicator

5.2.1 For hygienic hand disinfection and surgical hand disinfection, the microorganisms killing indicator shall comply with the provisions of GB 27950.

5.2.2 For skin disinfection, the microorganisms killing indicator shall comply with the provisions of GB 27951.

5.2.3 For ordinary objects surface disinfection, the microorganisms killing indicator shall comply with the provisions of GB 27952.

5.2.4 For medical items disinfection, the microorganisms killing indicator shall comply with the provisions of GB/T 27949.

8 Packaging, transportation and storage

8.1 The packaging shall be sealed.

8.2 Measures such as sun protection, rain protection, flame proof and explosion proof shall be adopted during transportation; it shall not be transported with toxic, harmful, flammable and explosive items or items that affect product quality. It shall avoid turning upside down when loading and unloading.

8.3 The storage shall be protected from light; it shall be placed in a cool, dry and ventilated place.

9 Symbols, labels and instructions

9.1 The packaging symbols shall comply with the provisions of GB/T 191.

9.2 The labels and instructions shall comply with the provisions of relevant specifications and standards on the labels and instructions of disinfection products.

9.3 Product precautions should have the following content:

- a) Use with caution if you are allergic to alcohol-containing preparations;
- b) Disinfectant for external use, do not take it orally, and place it in a place that is out of reach of children;
- c) Flammable, keep away from fire;
- d) Not suitable for air disinfection;
- e) Not suitable for the disinfection of the surface of fat-soluble objects;
- f) Use original solution, should not use after dilution.

10 Inspection methods

10.1 pH value

Test according to "Disinfection Technical Specifications" (2002 edition).

10.2 Active ingredient content

When the specific gravity method is applicable, the ethanol content is tested according to WS/T 535. When the specific gravity method is not applicable, the

Annex A

(normative)

Test method of ethanol and iso(n-)propanol content

A.1 Test method of ethanol content

A.1.1 General

The detection limit of this method is 0.03 %, the linear range of the method is 0.3 % ~ 2.0 %, the recovery rate of six additions is 98 % ~ 101 %, and the average recovery rate of addition is 99.5 %.

A.1.2 Chromatographic reference conditions

A.1.2.1 Chromatographic column

2.0 m × 4 mm glass column; stationary phase: GDX-102 0.2 mm ~ 0.3 mm (60 mesh to 80 mesh); column temperature: 180 °C; sample inlet temperature and detector temperature: 230 °C; carrier gas (N₂) flow rate: 45 mL/min; hydrogen flow rate: 45 mL/min; air flow rate: 450 mL/min.

A.1.2.2 Capillary column

DW-WAX: 30 m × 0.32 mm × 0.25 μm; column temperature: 60 °C, maintain for 10 min; column inlet: 230 °C, detector temperature: 230 °C, carrier gas (N₂) flow rate: 1.0 mL/min; hydrogen flow rate: 40 mL/min; air flow rate: 400 mL/min; split ratio: 60:1.

A.1.3 Preparation of standard solution

A.1.3.1 Volume fraction standard solution: prepare ethanol standard series with ethanol concentration (in volume fraction) of 0.1 %, 0.2 %, 0.3 %, 0.5 %, 1.0 % and 2.0 % respectively.

A.1.3.2 Mass concentration standard solution: prepare ethanol standard series with ethanol mass concentration of 1 g/L, 2 g/L, 3 g/L, 5 g/L, 10 g/L and 20 g/L respectively.

A.1.4 Content determination

A.1.4.1 Carry out pre-treatment of samples as needed.

A.1.4.2 For low-viscosity solution samples, it may take a certain volume, and dilute with pure water before test. For other samples, it shall take a certain mass, and test after made to constant volume with pure water.

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