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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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Hygiene requirements for skin disinfectant

皮肤消毒剂卫生要求

(English Translation)

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1 Scope

This Standard specifies technical requirements, test methods, use methods, labels and user manual as well as precautions for use of skin disinfectant.

This Standard is applicable to disinfectant for intact and damaged skin disinfection. It is not applicable to hand disinfectant.

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 601, Chemical Reagent - Preparations of Standard Volumetric

Solutions

GB/T 6680, General rules for sampling liquid chemical products

GB 15603, Rule for storage of chemical dangers

GB 15982, Hygienic standard for disinfection in hospitals

Pharmacopoeia of People's Republic of China

Disinfection technical specifications, Ministry of Public Health

Hygienic specifications for cosmetics, Ministry of Public Health

Specification for the management of label instructions for disinfection products, Ministry of Public Health

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

skin disinfection

Kill or remove pathogenic microorganisms on human skin and meet disinfection requirements.

b When it is estimated that the disinfectant has a sensitizing effect, this test is required.

4.3.5 Stability

The validity of the original packaged product is ≥ 12 months.

4.3.6 Requirements for disinfectants in use

The sensory traits, effective ingredient content, pH of the disinfectant in use after opening meet the product quality requirements. The total number of colonies ≤ 50 CFU/mL (g), mold and yeast ≤ 10 CFU/mL (g). It shall meet the requirements of GB 15982. Pathogenic bacteria (staphylococcus aureus, pseudomonas aeruginosa, hemolytic streptococcus) shall not be detected.

Disinfectant for damaged skin in use shall meet the exit-factory requirements.

5.1 Sensory traits examination

Visually inspect disinfectant color, clarity.

5.2 Determination of physical and chemical indicators

5.2.1

pH determination

Determine according to relevant methods in Disinfection technical specifications.

5.2.2 Active ingredient content

Determine according to relevant provisions in Disinfection technical specifications, GB 6680, GB/T 601.

5.2.3 Determination of lead, mercury and arsenic limits

Determine according to relevant methods in Hygienic specifications for cosmetics.

5.2.4 Stability test

Determine according to relevant methods in Disinfection technical specifications.

5.3 Microorganism killing test

Determine according to relevant methods in Disinfection technical specifications.

5.4 Identification of microbial contamination

See Annex A for inspections of total colony, mold and yeast, pathogenic bacteria and sterility.

5.5 Toxicology test

Determine according to relevant methods in Disinfection technical specifications.

6.1 Disinfection of intact skin

Use disinfectant to wipe or rub to disinfect 2~3 times. Act 1min~5min to achieve disinfection effect.

6.2 Disinfection of damaged skin

Use disinfectant to rub or rinse to disinfect. Act 1min~5min to achieve disinfection effect.

6.3 Disinfection of skin at injection or puncture site

Use disinfectant to wipe to disinfect 2~3 times. Act ≤ 1 min to achieve disinfection effect.

7 Labels and user manual

In accordance with relevant provisions of Specification for the management of label instructions for disinfection products.

8 Precautions for use

8.1

Protect from light. Seal. Keep away from moisture. Store in a cool, dry place.

8.2

Avoid use with antagonist drugs.

8.3

For allergy sufferers, use with caution.

8.4

Disinfectant for external use must not to be taken orally. Keep out of the reach of children.

8.5

After disinfection with iodine disinfectant, deiodination shall be conducted.

Annex A (normative)

Test methods for microorganism

A.1.1 Test equipment

A.1.1.1 Erlenmeyer flask. 250mL.

A.1.1.2 Measuring cylinder. 200mL.

A.1.1.3 Autoclave.

A.1.1.4 Level-100 clean room or level-100 laminar flow ultra-clean workbench.

A.1.1.5 Test tube. 15mm x 150mm.

A.1.1.6 Sterilization plate. 9cm in diameter.

A.1.1.7 Sterilization scale pipette. 10mL, 1mL.

A.1.1.8 Alcohol lamp.

A.1.1.9 Constant temperature incubator. $36^{\circ}\text{C}\pm 1^{\circ}\text{C}$.

A.1.1.10 Magnifier.

A.1.1.11 Saline.

A.1.1.12 Common nutrient agar medium.

A.1.1.13 Neutralizer.

A.1.2.1 Sample processing

Use a sterile pipette to pipette 1.0mL of disinfectant. Add into 9.0mL of sterile saline that contains corresponding neutralizing agent. Shake 20s or beat 80 times. Take 1.10 dilution for testing.