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NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA

ICS 11.080

C 50

GB/T 27947-2020

Replacing GB/T 27947-2011

Hygienic requirements for phenol disinfectant

酚类消毒剂卫生要求

Issued on: June 02, 2020

Implemented on: December 01, 2020

Issued by: State Administration for Market Regulation;

**Standardization Administration of the People's Republic of
China.**

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Hygienic requirements for phenol disinfectant

1 Scope

This Standard specifies raw materials and technical requirements, scope of application, methods for use, transport, storage and packaging, marking requirements, inspection methods for phenol disinfectant.

This Standard is applicable to the disinfectant that uses phenol, cresol, xyleneol, p-chloro-m-xyleneol, trichlorohydroxydiphenyl ether and other phenolic compound as the main raw materials, uses appropriate surfactant as solubilizer, uses ethanol, isopropanol, water as solvent, without other bactericidal ingredients.

This Standard is inapplicable to single or compound disinfectant that takes other phenolic compounds as main bactericidal ingredients.

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 and storage marks*

GB/T 2600, *Coking xyleneol*

GB 27950, *Hygienic requirements for hand antiseptic agents*

GB 27951, *Hygiene requirements for skin disinfectant*

GB 27952, *General requirements for ordinary objects surface disinfectant*

GB 27954, *General requirements for disinfectant of mucous membrane*

Pharmacopoeia of the People's Republic of China (Volume II, Volume IV, 2015)

Hygienic specifications for disinfection product manufacturers (2009)
[Ministry of Health (issued by Department of Legal Supervision, Ministry of Health (2009) No. 53]

Ethanol and isopropanol used as disinfectants for disinfection of hands, skin and mucous membranes shall meet the requirements of *Pharmacopoeia of the People's Republic of China (Volume II, 2015)*.

4.7 Water for production

Water for production shall meet the requirements for water for production in *Hygienic specifications for disinfection product manufacturers (2009)*.

4.8 Other raw and auxiliary materials

Other raw and auxiliary materials shall meet the corresponding sanitary standards, specifications and other relevant regulations. They shall have corresponding conforming certification materials.

5 Technical requirements

5.1 Active ingredient content

The active ingredient content shall meet the requirements of the label value.

5.2 pH value

The pH value shall meet the requirements of product enterprise standards or quality standards.

5.3 Lead, arsenic, mercury impurity limits as well as prohibited and restricted substances

For disinfectant for skin and mucous membrane disinfection, its lead, arsenic, mercury impurity limits as well as prohibited and restricted substances shall meet the requirements of GB 27950, GB 27951 and GB 27954.

5.4 Indicators of killing microorganisms

5.4.1 Microbial killing effect in laboratory

Select the corresponding microorganism according to the product disinfection object. According to the use concentration and action time specified in corresponding GB 27950, GB 27951, GB 27952, GB 27954, specifications and product instructions, the killing effect of microorganisms shall meet the requirements of Table 1.

Table 1 -- Requirements for killing microorganisms

Test microorganism	Killing or inactivate microorganism logarithm	
	Suspension method ^a	Carrier method ^b

7 Methods for use

7.1 General rules

Use according to the methods for use that are marked on the product label, the instruction manual.

7.2 Disinfectant containing phenol and cresol

After disinfecting and wiping the object surface and fabric, the action time shall not exceed 15min. The soaking and disinfection time shall not exceed 30min.

7.3 Disinfectant containing p-chloro-m-xlenol

7.3.1 Hygienic hand disinfection: smear or wipe disinfection; the action time shall not exceed 1min.

7.3.2 Skin disinfection: wipe disinfection; the action time shall not exceed 5min.

7.3.3 Object surface disinfection: the action time after wiping shall not exceed 15min; the soaking and disinfection time shall not exceed 30min.

7.3.4 Mucosal disinfection: wipe or rinse disinfection; the action time shall not exceed 5min.

7.4 Disinfectant containing triclosan

7.4.1 Hygienic hand disinfection: smear or wipe disinfection; the action time shall not exceed 1min.

7.4.2 Surgical hand disinfection: smear or wipe disinfection; the action time shall not exceed 5min.

7.4.3 Skin disinfection: smear or wipe disinfection; the action time shall not exceed 5min.

7.4.4 Mucosal disinfection: wipe or rinse disinfection; the action time shall not exceed 5min.

7.4.5 Object surface disinfection: after wiping or spraying, the action time shall not exceed 15min; soaking disinfection time shall not exceed 30min.

8 Transport, storage and packaging

8.1 The packaging, storage and transportation marks of the product shall meet the requirements of GB/T 191. Product loading-unloading shall be handled with

Annex A

(normative)

Method for determination of phenol content in disinfectant

A.1 Principle

Use volumetric analysis method. KBrO_3 and KBr produce Br_2 in acid medium. Br_2 has a substitution reaction with phenol to generate stable tribromophenol. The remaining Br_2 reacts with KI to produce I_2 . It can be $\text{Na}_2\text{S}_2\text{O}_3$ standard titrant. According to the difference between $\text{Na}_2\text{S}_2\text{O}_3$ standard titrant consumed by the blank (purified water instead of the sample) and $\text{Na}_2\text{S}_2\text{O}_3$ standard titrant consumed by the sample, calculate the content of phenol in disinfectant.

A.2 Methods

A.2.1 Preparation and calibration of sodium thiosulfate standard titration solution (0.1mol/L)

A.2.1.1 Preparation

Weigh 26g of sodium thiosulfate pentahydrate (or 16g of anhydrous sodium thiosulfate). Add 0.20g of anhydrous sodium carbonate. Dissolve in 1000mL of water. Slowly boil it to boil 10min. Cool it.

After 2 weeks of placement, use #4 glass colander to filter.

A.2.1.2 Calibration

Weigh 0.18g of working reference reagent potassium dichromate that has been dried at $120^\circ\text{C} \pm 2^\circ\text{C}$ to a constant amount. Put in an iodine measuring bottle. Dissolve in 25mL of water. Add 2g of potassium iodide and 20mL of sulfuric acid solution (20%). Shake them well. Place in a dark place for 10min. Add 150mL of water ($15^\circ\text{C} \sim 20^\circ\text{C}$). Use the prepared sodium thiosulfate solution to titrate. Add 2mL of starch indicator solution (10g/L) when it approaches to the end point. Continue to titrate until the solution turns from blue to bright green. Do a blank test at the same time.

Calculate the concentration of sodium thiosulfate standard titrant according to formula (A.1):

$$c = \frac{m \times 1\,000}{(V_1 - V_2) \times M} \dots\dots\dots (A.1)$$

Annex B

(normative)

Test method for cresol isomer content in disinfectant

B.1 Principle

Use chromatographic column to separate. Use hydrogen flame ionization detector to detect. Determine the nature according to the retention time. Quantify according to peak height or peak area.

B.2 Chromatographic reference conditions and system suitability test

Use 2% phosphoric acid-containing glycol polyester adipate as the stationary phase. Coating concentration is 4%~10%. Use hydrogen flame detector. Column temperature is 145°C. The temperature of the inlet and detector is 200°C.

B.3 Determination of calibration factor

Accurately weigh 1.3g of salicylaldehyde. Put in a 50mL volumetric flask. Add ether to dissolve and dilute to the scale. Shake well and use it as the internal standard solution. Accurately weighed 0.65g of ortho-cresol reference substance. Put in a 25mL volumetric flask. Add ether to dissolve and dilute to the scale. Shake well and use it as the reference solution. Precisely measure 5 mL of the reference solution and the internal standard solution respectively. Put in a plugged test tube. Seal and plug. Shake well. Take 1 μ L into the gas chromatograph. Calculate the correction factor for ortho-cresol. Multiply by 1.042. It shall be the correction factor for meta-cresol.

B.4 Sample determination

Precisely weigh 1.0g of this product and place it in a separating funnel. Add 0.1 mL of concentrated hydrochloric acid. Shake well. Add 3mL of water. Shake well. Precisely add 20mL of ether. Shake gently. Place still for stratification. Discard the water layer. Add 5mL of water. Shake gently. Conduct stratification. Discard the water layer. Precisely measure 5mL of ether extract and 5mL of internal standard solution in a plugged test tube. Shake well. Take 1 μ L into the gas chromatograph. Determine.

B.5 Calculation formulas

B.5.1 Calculation of o-cresol correction factor

Annex C

(normative)

Determination of p-chloro-m-xylene in disinfectant

C.1 Principle

P-Chloride m-xylene has UV absorption at 280nm wavelength. It may use reversed-phase high performance liquid chromatography (HPLC) to separate. Determine the nature according to the retention time. Quantify based on the peak area. This method is suitable for determining the active content of p-chloro-m-xylene in disinfectant.

C.2 Preparation of reagents

Methanol (chromatographically pure). Standard solution of p-chloro-m-xylene: weigh 0.1g of standard p-chloro-m-xylene; use a small amount of methanol to dissolve and dilute to 100mL; this solution contains 1g of p-chloro-m-xylene per 1L.

C.3 Chromatographic reference conditions

Chromatographic column: C₁₈ column (150mm×4.6mm, inner diameter is 5μm). Mobile phase: methanol/water (70/30); before analysis, filter through 0.45μm membrane and vacuum degas. Flow rate: 1.00mL/min. UV detection wavelength: 220nm. Column temperature: 25°C.

C.4 Drawing of standard curve

Use standard solution of p-chloro-m-xylene to prepare the series solutions of which the mass concentration is respectively 0mg/L, 200 mg/L, 400 mg/L, 600 mg/L and 800mg/L. Under the set chromatographic conditions, take 5μL respectively for analysis. Take the standard series mass concentration as the abscissa X and the peak area as the ordinate Y to perform linear regression processing, so as to obtain the linear equation.

C.5 Sample determination

If the labeled concentration of p-chloro-m-xylene in the disinfectant is too high, it needs to be properly diluted. Make the concentration after dilution within the linear range of the standard curve. For paste samples, it shall use the mobile phase to prepare an aqueous solution. Filter by 0.45μm membrane for use. Under the set chromatographic conditions, inject 5μL of sample solution for analysis. According to the peak area, calculate the corresponding p-chloro-m-

Annex D

(normative)

Determination of 2,4,4'-trichloro-2'-hydroxydiphenyl ether in disinfectant

D.1 Principle

2,4,4'-Trichloro-2'-hydroxydiphenyl ether has UV absorption at 280nm. It may use reversed-phase high performance liquid chromatography (HPLC) to separate. Determine the nature according to the retention time. Quantify based on the peak area.

D.2 Preparation of reagents

Methanol (chromatographically pure). 2,4,4'-Trichloro-2'-hydroxydiphenyl ether standard solution: weigh 0.1g of 2,4,4'-trichloro-2'-hydroxydiphenyl ether standard product; use a small amount of methanol to dissolve; set constant volume to 100mL; this solution contains 1g of 2,4,4'-trichloro-2'-hydroxydiphenyl ether per 1L.

D.3 Chromatographic reference conditions

The chromatographic reference conditions are as follows:

- a) Chromatographic column: C₁₈ column (150mm×4.6mm, inner diameter is 5μm);
- b) Mobile phase: methanol/water (80/20); before analysis, filter through 0.45μm membrane and vacuum degas;
- c) Flow rate: 1.5mL/min;
- d) UV detection wavelength: 280nm;
- e) Column temperature: 25°C.

D.4 Drawing of standard curve

Use 2,4,4'-Trichloro-2'-hydroxydiphenyl ether standard solution to prepare the series solutions of which the mass concentration is respectively 0 mg/L, 200 mg/L, 400 mg/L, 600mg/L and 800mg/L.

Under the set chromatographic conditions, take 5μL respectively for analysis. Take the standard series mass concentration as the abscissa X and the peak area as the ordinate Y to perform linear regression processing, so as to obtain

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