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

GB 27950-2020

Replacing GB 27950-2011

General requirements for hand disinfectant

手消毒剂通用要求

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Table of Contents

1	Scope
2	Normative references
3	Terms and definitions
4	Requirements for raw material
5	Technical requirements
5.3	Validity period
5.5	Safety index
6	Inspection methods
6.3	Validity period
6.5	Safety index testing
6.5.2	Determination of lead, arsenic, mercury content
7	Method of use
7.1	Hygienic hand antisepsis method Take an appropriate amount (about
8	Identification

Foreword

All technical contents of this standard are mandatory. This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces GB 27950-2011 "Hygienic requirements for hand disinfectants". Compared with GB 27950-2011, the main technical changes of this standard are as follows: - ADD normative references; - In terms and definitions, ADD the "Quick-dry hand disinfectant" and "Disposable hand disinfectant"; - MODIFY the requirements for raw material; - MODIFY the technical requirements; - MODIFY the inspection method; - MODIFY the surgical hand disinfection method to perform in accordance with WS/T 313. - ADD the normative appendix A "Method for testing the validity period of products after use". This standard was proposed by and shall be under the jurisdiction of the National Health Commission of the People's Republic of China.

Drafting organizations of this standard. Hunan Provincial Center for Disease Control and Prevention, Xiangya Hospital of Central South University, Comprehensive Supervision Bureau of Hunan Provincial Health Commission, Anhui Academy of Medical Sciences, Institute of Environmental and Health-related Product Safety of Chinese Center for Disease Control and Prevention, Zhejiang Provincial Diseases Prevention and Control Center, Chinese People's Liberation Army Air Force Medical Center, Shenzhen Center for Disease Control and Prevention, Xinjiang Uygur Autonomous Region Center for Disease Control and Prevention, Turpan City Center for Disease Control and Prevention, Peking University

First Hospital, Changsha First Hospital, General People's Liberation Army Hospital, Shaoshan People's Hospital, Shaoshan Health Center. The main drafters of this standard. Chen Guiqiu, Xu Qinghua, Wu Anhua, Li Aibin, Chen Peihou, Ban Haiqun, Hu Guoqing, Cao Jingui, Zhu Zili, Yin Jin, Song Jiangnan, Gao Qiong, Li Shikang, Yi Liang, Yang Hongcai, Song Yan, Guan Xiaodong, Li Liuyi, Pan Huiqiong, Guo Xiaomin, Zhao Zhihong, Nie Xinzhang, Huang Yehui, Liu Aibing, Shi Shaoyi, Song Hengzhi, Mo Jiwei, Liu Xuejun, Guo Jiguang, Zhang Zhichao, Fang Weizheng, Zhou Hailin. This standard replaces the standard previously issued as follows: - GB 27950-2011. General requirements for hand disinfectant

1 Scope

GB 27950-2020 is the Chinese national standard on general requirements for hand disinfectant, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 9 April 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 November 2020. Classification: ICS 11.080, CCS C50. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This standard specifies the raw material requirements, technical requirements, inspection methods, methods of use, identification of hand disinfectants. This standard applies to disinfectants for sanitary hand disinfection and surgical hand disinfection.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this standard.

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

GB 15982 Hygienic standard for disinfection in hospitals WS/T 313 Standard for hand hygiene for healthcare workers in healthcare settings

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Hand antisepsis Treatment process of killing or removing hand microorganisms and

achieving a harmless state.

Note. It can be divided into sanitary hand antisepsis and surgical hand antisepsis.

3.2 Hand disinfectant Chemical preparation applied to hand antisepsis.

3.3 Alcohol-based hand rub Hand disinfectant containing alcohol and skin care ingredients.

3.5 Hygienic hand antisepsis The process of rubbing your hands with a hand disinfectant to reduce the temporary bacteria in the hands.

3.6 Surgical hand antisepsis The process that, before the surgery, the medical staff rubbed and washed hands with running water and hand washing liquid, then used hand disinfectant to remove or kill temporary resident bacteria and reduce resident bacteria.

4 Requirements for raw material

4.1 The raw materials shall meet the quality requirements of the Pharmacopoeia of the People's Republic of China (2015 edition) or medical grade or food grade or other corresponding standards.

5 Technical requirements

5.1 Active ingredient content The content of active ingredients shall meet the requirements of national standards or quality standards of the corresponding products.

5.2 pH value The pH value of the hand disinfectant shall be within ± 1 of the marked value.

5.3 Validity period

5.4 Microbial kill indicator The effect of microbial killing indicators according to the characteristics of the hand disinfectant product shall meet the requirements of Table 1.

5.5 Safety index

5.5.1 Toxicological requirements The toxicological indicators are as shown in Table 2.

5.5.2 Limit requirements for lead, arsenic, mercury Lead < 10 mg/kg, arsenic < 2 mg/kg, mercury < 1 mg/kg.

5.5.3 Requirements for banned substances Hand disinfectant formulations must not add hormones, antibiotics, antifungal drugs and their namesake ingredients [except for the disinfection and antiseptic drugs as listed in the Pharmacopoeia of People's Republic of China (2015 edition)] and the banned substances prescribed by the national health and health authorities.

6 Inspection methods

6.1 Active ingredient content It is determined according to the "Technical specifications for disinfection " (2002 edition) and national standards and other relevant methods.

6.2 pH It is determined according to the method of "Technical specifications for disinfection" (2002 edition)

6.3 Validity period

6.4 Microbial killing test Carry out the test according to "Technical specifications for disinfection" (2002 edition).

6.5 Safety index testing

6.5.1 Toxicological safety test Carry out the test according to "Technical specifications for disinfection" (2002 edition).

7.1 Hygienic hand antisepsis method Take an appropriate amount (about

2.0 mL) of hand disinfectant on the palm. Rub your hands together to evenly coat each part. Rub and disinfect for

8 Identification

8.1 The marking shall comply with the provisions of GB/T 191.