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

WS/T 628-2018

**Technical requirements for the hygiene and safety evaluation of
disinfectant products
(English Translation)**

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Foreword

5.2.6 of this standard is a recommended clause and the rest are mandatory.

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard is mainly drafted by. Jiangsu Provincial Health Supervision Institute, China Center for Disease Control and Prevention, Environmental and Health-related Product Safety Institute, Mountain Eastern Provincial Health and Family Planning Supervision Office, Jiangxi Provincial Health and Family Planning Supervision Office, Jiangsu Provincial Center for Disease Control and Prevention.

1 Scope

This standard specifies the basic requirements and contents of the sanitary safety evaluation of disinfection products.

This standard applies to the first and second types of disinfection products other than the new disinfection products produced, operated and used within the territory of the People's Republic of China.

Hygiene safety evaluation of products (disinfectants, disinfection equipment, indicators, anti-bacterial preparations).

This standard does not apply to the hygienic safety evaluation of custom disinfection

equipment.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

Sanitary Safety Evaluation Specification for Disinfectants and Disinfecting Equipment for Drinking Water (Trial) (2005 Edition) Ministry of Health (Wei Supervision issued [2005] no. 336)

3 Terms and definitions

The following terms and definitions apply to this document.

Hygiene and safety evaluation of disinfectant product Comprehensive evaluation of the effectiveness and hygienic safety of disinfection products, including product label (nameplate), instructions, inspection Reports, corporate standards or quality standards, production enterprise health permits (certificates and customs declarations for overseas production and sales), disinfectants, Product formula of indicator and anti-bacterial preparation, structure diagram of disinfection apparatus, etc.

Responsible entity

Individuals, legal persons and other organizations that bear the liability for personal injury or property damage caused by product defects in accordance with the law. Commissioned production when processing, specifically refers to the entrusting party, the responsible unit of imported products is the responsible unit in China.

The first type of disinfection product class I disinfectant product High-level disinfectants and disinfection devices, sterilizing agents and sterilization devices for medical devices, skin/mucosal disinfectants, biological indicators, Sterilization effect chemical indicator.

The second type of disinfection product class II disinfectant product Disinfectants, disinfection devices, chemical indicators, and sterilized articles with sterilization marks, anti-(restrictive) Bacterial preparation.

Customized disinfection instrument Designed and manufactured for a single project, there is no non-stereoscopic disinfection device for mass production.

Sterilization process verification device process challenge device; PCD A simulated device with predetermined resistance to the sterilization device for evaluating the effectiveness of the sterilization process. Chemically placed inside a chemical indicator PCD, called bio-PCD when placing biological indicators.

4 Basic requirements

4.1

The product responsible unit shall conduct a sanitary safety evaluation before the first-class and second-class disinfection products are first listed, and form a sanitary product for disinfection products.

The full evaluation report is responsible for the evaluation results.

4.2

The complete "Sanitary Safety Evaluation Report for Disinfecting Products" includes the basic situation table and evaluation materials. The format is shown in Appendix A.

4.3

If the basic situation of the "Sanitary Safety Evaluation Report for Disinfecting Products" is changed, the corresponding contents shall be updated in a timely manner.

4.4

Prior to the initial release of the disinfection product, the product responsible unit shall carry out physical and chemical indicators, killing/inhibiting microbial indicators and according to different product categories.

(or) detection of microbiological indicators, toxicological safety indicators, indicator technical indicators, and responsible for the authenticity of the product.

4.5

After the disinfection products that have completed the hygienic safety evaluation are listed, the product formula or structure diagram (main components and parameters) and the hygienic quality of the products. If the closely related indicators change, the health safety assessment should be repeated.

4.6

After the listing, the disinfection products are changed in the following situations. The product responsible unit shall re-test and update the evaluation materials for the relevant inspection items.

- a) The actual production address is transferred, another branch or workshop is set up, and the production and processing are transferred to the company;
- b) Disinfectants, antibacterial preparations, biological indicators, chemical indicators, sterilized packaging with sterilization labels and PCD Extend the expiration date of the product;
- c) disinfectants, disinfection devices and anti-bacterial agents increase the scope of use or change the method of use;

d) The first category of disinfection products health safety evaluation report before the expiration of the four-year period.

5.1 Label (nameplate), instructions

It should meet the requirements of the relevant specifications and standards for the labeling instructions for disinfection products.

5.2 Inspection report

5.2.1

The inspection report of two testing institutions shall be provided without the inspection method of measurement certification.

5.2.2

All inspection items should be completed using the same batch of products, and different batches can be used for the supplementary inspection items, and the effective measurement can be re-measured.

The content of the product, the pH value, and the product whose active ingredient is not purely chemical component should be re-measured to kill a microorganism with the strongest resistance (or Test) and pH.

5.2.3

Prior to the initial listing of the disinfection products, the inspection items shall comply with Appendix B, Appendix C, Appendix D, Appendix E, and Appendix according to different categories of products.

F. Requirements of Appendix G.

5.2.4

The re-inspection of disinfection products after listing is as follows.

- In case of 4.6 a), the disinfectant and anti-bacteria preparations should be tested for active ingredient content, stock solution stability test and pH value.

The disinfection equipment shall be tested for the strength of the main bactericidal factors. If the conditions for determining the bactericidal factors are not met, the simulated field test shall be carried out;

The biological indicator shall be tested for the amount of bacteria, the chemical indicator shall be determined for the color change, and the sterilization with the sterilization mark the packaging of the product should be tested for the penetration of the sterilization factor.

- In case of 4.6 b), the disinfectant and anti-bacteria preparations should have the active ingredient content, pH value, and the strongest resistance.