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

GB 38598-2020

**General requirement for label and instruction book of
disinfection products**

消毒产品标签说明书通用要求

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Foreword

This Standard was drafted in accordance with the rules in GB/T 1.1-2009. This Standard was proposed by and shall be under the jurisdiction of National Health Commission of the People's Republic of China. General Requirement for Label and Instruction Book of Disinfection Products

1 Scope

GB 38598-2020 is the Chinese national standard on general requirement for label and instruction book of disinfection products, 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 17 November 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 December 2021. 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 general requirements for labels and instruction books of disinfectants, disinfection apparatuses, indicators and sanitary products, and the requirements for the marking of various indicators. This Standard is applicable to disinfection products produced, sold and used within the territory of the People's Republic of China. This Standard is not applicable to exported disinfection products not sold or used in the country.

2 Normative References

The following documents are indispensable to the application of this document. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 190 Packing Symbol of Dangerous Goods

GB/T 191 Packaging - Pictorial Marking for Handling of Goods

GB 15979 Hygienic Standard for Disposable Sanitary Products Technical Standard for Disinfection (Version 2002) (National Health Commission of the People's Republic of China)

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 Disinfection Products Disinfection products refer to products related to human health and included in the classification catalog of disinfection product production categories, such as. disinfectants, disinfection apparatuses, indicators and sanitary products, etc.

3.2 New Disinfection Products New disinfection products refer to disinfectants and disinfection apparatuses produced with new materials, new processes and technology, and new sterilization principles.

3.3 Disinfectant Disinfectant refers to an agent used to kill microorganisms on the media to achieve disinfection or sterilization requirements.

3.4 Disinfection Apparatus Disinfection apparatus refers to a device or equipment (excluding indicators) used to kill microorganisms on the media to achieve disinfection or sterilization requirements.

3.5 Biological Indicator Biological indicator refers to a test system that has specific resistance to the prescribed sterilization process and contains live microorganisms.

3.6 Chemical Indicator Chemical indicator refers to a test system that displays changes in one or more pre- determined process variables in accordance with the chemical or physical changes generated by the exposure to a certain sterilization process.

4 Requirements for Disinfectants

4.1 The label of minimum sales packaging shall indicate the following contents.

4.2 The label of transport package shall indicate the following contents.

4.3 The instruction book shall indicate the following contents.

4.4 The label and instruction book shall not indicate the following contents.

5 Requirements for Disinfection Apparatuses

5.1 The nameplate shall indicate the following contents.

5.2 The label of transport package shall indicate the following contents.

5.3 The instruction book shall indicate the following contents.

5.4 The label and instruction book shall not indicate the following contents.

6 Requirements for Indicators

6.1 The label of minimum sales packaging shall indicate the following contents.

6.2 The label of transport package shall indicate the following contents.

6.3 The instruction book shall indicate the following contents.

7 Requirements for Sanitary Products

7.1 The label of minimum sales packaging shall indicate the following contents.

7.2 The label of transport package shall also indicate the following contents.

7.3 The instruction book [antibacterial (bacteriostat) agent, contact lens care products] shall also indicate the following contents.

7.4 The label and instruction book of antibacterial (bacteriostat) agent, contact lens care products, wet wipes and hygiene wet wipes shall not indicate the following contents.

7.4.4 The label of hygiene wet wipes shall not indicate. sterilization, disinfection, bactericidal, degerming, medicine, high efficiency, prevention of venereal diseases, treatment of diseases, reduction or alleviation of disease symptoms, anti-inflammation and inflammation-diminishing; the product name shall not be marked with the text "antibacterial".

7.4.5 The label of other sanitary products shall not indicate the following contents.

8 Requirements for the Marking of Various Indicators

8.1 The Chinese marking of label and instruction book shall be standardized Chinese characters (excluding registered trademarks), and shall comply with the following requirements.

8.2 The contents marked by the label and instruction book shall be authentic. The therapeutic effect on diseases, the clinical symptoms of diseases, the names of diseases (except when the name of a disease is part of the name of a microorganism), the names of

antibiotics, the names of hormones and antifungal medicines, and other substances prohibited by the national health administration shall not be indicated or implied through marking.

8.3 The product name shall comply with the following requirements.

8.4 The information of product sanitary license shall comply with the following requirements.

8.5 The product specification and net mass shall comply with the following requirements.

8.6 The marking of the main effective ingredients and their contents, the main bactericidal factors and their intensity, or the names of main raw materials and the added amounts shall comply with the following requirements.

8.7 The types of microorganisms to be killed or inhibited shall comply with the following requirements.

8.8 The scope of application shall comply with the following requirements.

8.9 The method of use shall comply with the following requirements.

8.10 Matters needing attention shall comply with the following requirements.

8.16 In terms of disinfectants, disinfection apparatuses, indicators, antibacterial agents, bacteriostats and contact lens care products, there shall be an attached instruction book in the minimum sales packaging. If the content of the product label already contains the instruction book, the instruction book may not be attached.

8.17 Please refer to Appendix A for the content marked in the label and instruction book.