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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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General Requirement for Label and Instruction Book of Disinfection Products

1 Scope

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)

Regulations on Naming Health-related Products [supervised and issued by National Health Commission of the People's Republic of China (2001) No. 109]

Measures for the Supervision and Management of Quantitative Packaging Commodities [Decree of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (2005) No. 75]

List of Hazardous Chemicals (State Administration of Work Safety, No. 10 Department Announcement, Year 2015, No. 5)

Sterilization packaging material refers to packaging material for terminally sterilized medical devices with sterilization marks.

3.8 Antibacterial Agent

Antibacterial agent refers to an agent that directly contacts the intact human skin or mucous membrane and has a certain bactericidal effect.

3.9 Bacteriostat

Bacteriostat refers to an agent that directly contacts the intact human skin or mucous membrane and has a certain antibacterial effect.

3.10 Wet Wipe

Wet wipe refers to a product that takes non-woven fabrics, fabrics, wood pulp composites, and wood pulp papers as the carrier, adds appropriate amounts of raw materials, such as: production water, preservatives or other auxiliary ingredients, and has a cleansing effect on objects to be treated (such as: hands, skin, mucous membranes and the surface of ordinary objects).

3.11 Hygiene Wet Wipe

Hygiene wet wipe refers to a wet wipe that takes non-woven fabrics, fabrics, wood pulp composites, and wood pulp papers as the carrier, adds appropriate amounts of raw materials, such as: production water and disinfectants, and has a cleansing and bactericidal effect on objects to be treated (such as: hands, skin, mucous membranes and the surface of ordinary objects).

3.12 Other Sanitary Product

Other sanitary product refers to various daily necessities that are discarded after use, in direct contact with the human body, and used for the purpose of human physiological hygiene or health care (antibacterial or bacteriostatic).

NOTE: it includes sanitary napkins, sanitary pads, tampons (built-in tampons), diapers, nappies (pads and papers), changing pads, tissues (papers), sanitary cotton (sticks, swabs and balls), cotton pads (papers and tissues), hand (finger) gloves, paper tableware, etc., among which, tissues (papers) include facial tissues, napkins, handkerchiefs, hand towels and sanitary papers (excluding toilet papers), etc.

3.13 Disinfection Sanitary Product

Disinfection sanitary product refers to a sanitary product that has been treated with ethylene oxide, ionizing radiation, pressure steam or other effective disinfection methods, and has reached the disinfection level of requirements specified in GB 15979.

3.22 Package Specification

Package specification refers to the number of products in the product transport package.

3.23 Valid Period

Valid period refers to a period, during which, the stability of disinfection product can meet the specified requirements under the specified storage conditions.

3.24 Shelf Life

Shelf life refers to the period for maintaining the quality of disinfection product under the conditions specified in the disinfection product standard and label.

NOTE: during this period, disinfection product shall comply with the quality prescribed in the product standard and label.

3.25 Machine Service Life

Machine service life refers to the working time of disinfection apparatus from normal use to loss of function.

NOTE: the unit is in years.

3.26 Main Component Service Life

Main component service life refers to the cumulative working time of the main components of disinfection apparatus from normal use to the main bactericidal factors or main technical parameters being reduced to the lower limit of the rated value.

NOTE: the unit is in hours, or months and years.

3.27 Responsibility Unit

Responsibility unit refers to a legal entity that is legally responsible for the compensation for personal injury or property loss to others due to product defects.

NOTE: when production is entrusted, the responsibility unit specifically refers to the entrusting party; when a branch (subsidiary) company under the same group does not have an independent legal person status, or a branch factory or product workshop under the same manufacturing enterprise does not have an independent legal person status is in production, the responsibility unit specifically refers to the group or manufacturing enterprise.

3.28 Responsibility Unit in China

Responsibility unit in China refers to the unique responsibility unit that is legally registered for imported products within the territory of China.

c) Product specification (tablets);

d) Main effective ingredients and their contents;

e) Types of microorganisms to be killed;

f) Scope of application (disinfectants used in the mucous membrane shall also be marked “only for diagnosis and treatment in medical and health institutions”);

g) Method of use;

h) Matters needing attention;

i) Valid period;

j) Serial No. of implemented standard;

k) Name, address and contact information of the manufacturing enterprise;

l) Sanitary license No. of the manufacturer of domestic products;

m) Country or region of origin of imported products.

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

a) Anti-inflammation, inflammation-diminishing, treatment of diseases, reduction or alleviation of clinical symptoms of diseases, description or explanation of disease symptoms, prevention of venereal diseases, spermicide and contraception;

b) Used for human feet, eyes, nails, axilla, scalp, hair, nasal mucosa and anorectal area;

c) × days is a course of treatment or follow the doctor’s advice; prevent recurrence; conducive to wound healing; assist with medicine treatment.

5 Requirements for Disinfection Apparatuses

5.1 The nameplate shall indicate the following contents:

a) Product name;

b) Sanitary license No. of new disinfection product;

c) Main technical parameters;

d) Main bactericidal factors and their intensity (when there is no detection

j) Machine service life or main component service life;

k) Serial No. of implemented standard;

l) Name, address and contact information of the manufacturing enterprise;

m) Sanitary license No. of the manufacturer of domestic products;

n) Country or region of origin of imported products;

o) Product installation and debugging method, and schematic diagrams of various function keys.

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

a) Treatment of diseases, reduction or alleviation of disease symptoms;

b) Assist with medicine treatment.

6 Requirements for Indicators

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

a) Product name;

b) Sanitary license No. of new disinfection product;

c) Net mass;

d) Bacteria content (biological indicator);

e) Scope of application;

f) Production date and valid period or production batch No. and expiration date;

g) Name, address and contact information of the manufacturing enterprise;

h) Sanitary license No. of the manufacturer of domestic products;

i) Country or region of origin of imported products;

j) Storage conditions.

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

a) Product name;

b) Package specification;

d) Sanitary license No. of the manufacturer of domestic products;

e) Country or region of origin of imported products;

f) Production date and valid period (wet wipes, contact lens care products without disinfection function and other sanitary products shall be marked with a shelf life) or production batch No. and expiration date;

g) Storage conditions (other sanitary products when necessary);

h) Antibacterial (bacteriostat) agent shall also be marked with effective ingredients and their contents, and the scope of application (for the purpose of pudendal mucosa, it shall also be marked “not used for the prevention of sexually transmitted diseases in sexual life”);

i) Contact lens care products shall also be marked with the main effective ingredients and their contents (those with disinfection effect), and the scope of application;

j) Wet wipes shall also be marked with product specification, names of main materials, and the serial No. of implemented standard;

k) Hygiene wet wipes shall also be marked with product specification, names of main materials, the serial No. of implemented standard, the main effective ingredients and their contents in the extruded liquid of hygiene wet wipes (the bactericidal factor with adsorption is the production liquid), the types of microorganisms to be killed, and the scope of application;

l) Other sanitary products shall also be marked with the types of microorganisms to be killed [antibacterial sanitary napkins (pads and papers)], the types of microorganisms to be inhibited [bacteriostatic sanitary napkins (pads and papers)], product specification, names of main materials, and the serial No. of implemented standard; disinfection-grade products shall also be marked with the text “disinfection-grade”, disinfection method and disinfection date.

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

a) Product name;

b) Package specification;

c) Name, address and contact information of the manufacturing enterprise;

d) Sanitary license No. of the manufacturer of domestic products;

e) Country or region of origin of imported products;

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.

7.4.1 The label and instruction book of antibacterial (bacteriostat) agent shall not indicate the following contents:

a) Anti-inflammation, inflammation-diminishing, treatment of diseases, reduction or alleviation of disease symptoms, description or explanation of disease symptoms, prevention of venereal diseases;

b) Applicable to damaged skin, damaged mucosa and wounds, etc.

c) High efficiency, disinfection, sterilization, degerming, spermicide and contraception;

d) Used for human feet, eyes, nails, axilla, scalp, hair, nasal mucosa and anorectal area;

e) × days is a course of treatment or follow the doctor's advice; prevent recurrence; conducive to wound healing; assist with medicine treatment.

7.4.2 The label and instruction book of contact lens care products shall not indicate the following contents:

a) Full-function, high efficiency, sterilization and degerming;

b) Treatment of diseases, reduction or alleviation of disease symptoms, assist with medicine treatment.

7.4.3 The label of wet wipes shall not indicate: sterilization, disinfection, antibacterial, bactericidal, antiseptic, degerming, medicine, high efficiency, prevention of venereal diseases, treatment of diseases, reduction or alleviation of disease symptoms, anti-inflammation and inflammation-diminishing.

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:

a) The label of sanitary products, such as: sanitary napkins, sanitary pads, sanitary papers, diapers (pads and papers), changing pads and nappies shall not be marked with disinfection, sterilization, degerming, prevention of vaginal discharge, dehumidification, moisturizing, anti-inflammation, inflammation-diminishing, spermicide and contraception;

e) The following content shall not be included in the product name: false, exaggerated and absolutized words, foreign letters, pinyin and symbols (except in the expression of a model), etc. If it is a registered trademark, or when foreign letters and symbols shall be used, it shall be expressed in Chinese in the label and instruction book, or in Chinese in the product name.

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

a) Domestic products shall be marked with a valid sanitary license No. of the actual manufacturing enterprise;

b) New disinfection products shall be marked with a valid sanitary license No.

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

a) The product specification shall comply with product characteristics;

b) The net mass shall accurately reflect its actual content; the tolerance of net mass shall comply with the provisions of Measures for the Supervision and Management of Quantitative Packaging Commodities. If there are multiple pieces of the same quantitatively packaged product in the same minimum sales packaging, then, the net content and total number of single-piece quantitatively packaged products shall be marked.

NOTE: the marking of net mass shall include “net mass” (in Chinese), figures and legal measurement units (or counting units expressed in Chinese).

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:

a) On the visible surface of the minimum sales packaging, the names and contents of the main effective ingredients, the main bactericidal factors and their intensity, or the names of main raw materials and the added amounts shall be marked;

b) If the main effective ingredients are chemical ingredients, the standardized chemical names and their contents shall be marked, among which, the effective ingredient content of liquid chemical disinfectant shall be expressed in mg/L, g/L or % (mass fraction or volume fraction); the effective ingredient content of solid chemical disinfectant shall be expressed in mg/tablet, g/tablet or mg/kg, g/kg or % (mass fraction);

c) If the main effective ingredients are plant ingredients, the Chinese scientific names of the plants and the amounts added in the unit volume shall be

b) The object of use of new disinfection products shall be consistent with the product's sanitary license approval;

c) In terms of disinfection products that need to receive the health and safety evaluation, the object of use shall be consistent with the product's health and safety evaluation report;

d) The object of use of other disinfection products shall comply with the stipulations of relevant standards.

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

a) The method of use shall be clear and specific, which may be expressed in texts or diagrams. When there are more than two methods of use, the specific requirements of each method of use shall be separately listed.

b) The method of use for disinfectants shall include the object of use, the preparation method (including the name of water used for dilution and the dilution ratio, etc., except for products used in the original solution. The preparation method of disinfectants of multi-package shall include the added amount of each package, the mixing time, the storage conditions and the longest use time of the liquid after preparation), the working concentration [expressed in the content of effective (active) ingredients, except for plant ingredients], the action time and the mode of use. In terms of disinfectants with special requirements for the object of use, the method of use shall also include residue-removing methods after disinfection or sterilization.

c) The method of use of antibacterial agents or bacteriostats, and contact lens care products shall include the preparation methods (except for products used in the original solution), the working concentration (expressed in the content of effective ingredients, except for plant ingredients), the action time (if the antibacterial ring test is used as the inspection method, then, it may not be marked) and the mode of use.

d) The method of use of disinfection apparatuses shall include the object of use, the mode of use, the action time and the conditions of use (for the disinfection apparatuses used for air disinfection, the usable area or volume shall also be marked; for other disinfection apparatuses, the loading requirements shall also be marked). If the disinfection effect is produced by a disinfectant, the working concentration of the disinfectant shall also be marked. For the object of use with special requirements for the residue of bactericidal factors, the method of use shall also include residue-removing methods after disinfection or sterilization.

e) The method of use of new disinfection products shall be consistent with the product's sanitary license approval.

d) Disinfectants used for multiple consecutive times shall also be marked with the valid period for multiple consecutive uses.

8.12 The production date, production batch No. and expiration date shall comply with the following requirements:

a) They shall be marked on the visible surface of the minimum sales packaging, and shall be clear and easy to identify;

b) The production date and expiration date shall be marked in year, month and date;

c) The marking form of production batch No. shall be determined by the manufacturing enterprise; the production batch No. of disinfection apparatuses may be consistent with the product serial No. or exit-factory No.

8.13 The implemented standard of disinfection products shall be national standards of related products, or enterprise standards that have been self-declared and disclosed on the public service platform of national enterprise standard information. The serial No. of implemented standard may not be marked with the year number. The enterprise standards shall comply with the requirements of relevant national laws, standards and specifications.

8.14 The name, address and contact information of the manufacturer of domestic products shall comply with the following requirements:

a) The name, registered address and actual production address of the manufacturer of domestic products shall be consistent with the manufacturer's sanitary license;

b) For disinfection products entrusted to be produced, the responsibility unit (the entrusting party) and its name, address and contact information, as well as the actual manufacturing enterprise (the entrusted party) and its name and address shall be simultaneously marked;

c) For disinfection products produced by a branch (subsidiary) company under the same group that does not have an independent legal person status, or a branch factory or product workshop under the same manufacturing enterprise that does not have an independent legal person status, the product's responsibility unit, and the name and address of the actual producer shall be respectively marked;

d) The contact information shall be marked with the telephone number of the manufacturing enterprise, etc.

8.15 The name, address and contact information of the manufacturer of imported products shall comply with the following requirements:

Appendix A

(informative)

Examples of Labels and Instruction Books of Disinfection Products

A.1 Product Name

A.1.1 Disinfectant

A.1.1.1 Product name of single-purpose disinfectant or disinfectant with single effective bactericidal ingredient, such as: "××® Skin and Mucous Membrane Disinfectant", "××™ Glutaraldehyde Disinfectant", "×× Brand Trichloroisocyanuric Acid Disinfection Tablet" and "××® Iodophor Disinfectant", etc.

A.1.1.2 Product name of multi-purpose disinfectant or disinfectant with multiple effective bactericidal ingredients, for example: "×× Brand Disinfectant".

A.1.1.3 Product name that does not comply with this Standard, such as: "×× Brand Disinfectant of Generation ×" and "Condyloma Acuminata External Use Disinfectant".

A.1.2 Disinfection apparatus

A.1.2.1 Product name of disinfection apparatus, such as: "××™ CGC-5g Ozone Generator", "××® AEOW-1000 Acidic Oxidation Potential Water Generator", "×× Brand Y-1000 Ultraviolet Air Sterilizer" and "×× Brand CPF-100 Chlorine Dioxide Generator", etc.

A.1.2.2 Product name of multi-purpose disinfection apparatus or disinfection apparatus with multiple effective bactericidal factors, for example: "×× Brand YKX-2000 Disinfection Machine (apparatus)".

A.1.3 Indicator

A.1.3.1 Product name of chemical indicator, such as: "××® 132 °C Pressure Steam Sterilization Chemical Indicator Card", "××™ Glutaraldehyde Disinfectant Concentration Chemical Indicator Card", "×× Brand Ultraviolet Radiation Intensity Indicator Card", etc.

A.1.3.2 Product name of biological indicator, for example: "××® Ethylene Oxide Sterilization Effect Biological Indicator".

A.1.3.3 Product name of sterilization packaging material with the mark of sterilization, such as: "××® Plasma Sterilization Packaging Material with Sterilization Mark" and "×× Brand Pressure Steam Sterilization Packaging Material and Roll with Sterilization Mark", etc.

bottle.

A.2.3.2 Chemical indicator card, for example, with a package specification of 20 pieces per box.

A.2.3.3 Air sterilizer, for example, with a package specification of 1 set.

A.2.4 Net mass

A.2.4.1 Disinfectant, for example, with a net mass of 100 mL.

A.2.4.2 Sanitary napkin, for example, with a net mass of 20 pieces.

A.2.4.3 Facial tissue, for example, with a net mass of 10 draws.

A.3 Main Effective Ingredient Content and Main Bactericidal Factor Intensity

A.3.1 Main effective ingredient content, for example, effective chlorine content is 18.0% ~ 22.0% (mass fraction), which may also be expressed as 180 g/L ~ 220 g/L.

A.3.2 Main bactericidal factor intensity, for example, ozone concentration is 16.0 mg/m^3 ~ 20.0 mg/m^3 (when there is no detection method, DO NOT mark it).

A.3.3 The amount of raw materials added per unit volume of plant ingredients, for example, take honeysuckle plant extract as the raw material, and the added amount is 2%.

A.3.4 Main effective ingredient content of antibacterial hand sanitizer, for example, the content of chlorhexidine is 0.18% ~ 0.22% (mass fraction), which may also be expressed as 1.8 g/L ~ 2.2 g/L.

A.3.5 Main effective ingredient content of contact lens care product, for example, polyhexanide biguanide 1.6×10^{-3} mg/L ~ 2.0×10^{-3} mg/L.

A.3.6 Main effective ingredient content of hygiene wet wipe, for example, the content of chlorhexidine acetate is 0.24% ~ 0.28% (mass fraction), which may also be expressed as 2.4 g/L ~ 2.8 g/L.

A.4 Product's Sanitary License Information

A.4.1 Manufacturer's sanitary license No., for example: (abbreviation of province, autonomous region, municipality directly under the Central Government) Wei Xiao Zheng (year) No. ××××.

A.4.2 New disinfection product's sanitary license approval, for example: Wei Xiao Xin Zhun (year) No. ××××.

A.5 Types of Microorganisms to be Killed or Inhibited (determine corresponding microorganism types by detection content)

shall be kept out of the reach of children;

b) DO NOT mix this product with other chemical substances, which would affect the effect;

c) This product is irritating to the skin, so please wear gloves when using it; after touching the mucous membrane, immediately rinse it, and seek medical advice if necessary;

d) It has a bleaching effect on cotton, linen and silk fabrics, etc.;

e) This product is corrosive to metals, so use it with caution;

f) Prepare it right before use;

g) Store it in a cook, dry and well-ventilated place; DO NOT store it together with acids, organics or combustibles.

A.9 Production Date / Valid Period (shelf life), Production Batch No. / Expiration Date

A.9.1 Products with a production date of May 3, 2017 shall be marked as “May 3, 2017” or “20170503”.

A.9.2 Products with a valid period (shelf life) of 2 years shall be marked as “2 years” or “24 months”.

A.9.3 Products with the production date as the batch No., for example, products of May 2, 2017, shall be marked as “20170502” or “20170502 + identification code”.

A.9.4 Products with an expiration date of April 1, 2017 shall be marked as “expiration date 20170331”.

A.10 Machine Service Life or Main Component Service Life

A.10.1 Machine service life may be marked as “× year”.

A.10.2 Main component service life may be expressed in the mode “×× month” or “×× h”, etc.

A.11 Serial No. of Implemented Standard

The serial No. of implemented standard of hygiene wet wipe is: “WS 575”.

A.12 Name and Address of Manufacturing Enterprise

A.12.1 Domestic products

A.12.1.1 The name of the manufacturing enterprise shall be consistent with the name

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