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Wet wipes and similar products - Part 3: Particular requirements for disinfection wet wipes

湿巾及类似用途产品 第3部分:消毒湿巾专用要求

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Table of Contents

1 Scope

The document sets the requirements, the inspection rules and the requirements for marking, packaging, transport and storage of disinfection wet wipes, defines the related terms, gives the product classification and describes the matching test methods.

It applies to the production, inspection and sale of disinfection wet wipes for everyday use made from non-woven fabric, airlaid paper or other raw materials. It does not apply to disinfection wet wipes for medical settings or for medical devices.

3 Terms and definitions

Disinfection is the killing or removal of pathogenic micro-organisms on a transmission medium so that the medium becomes harmless. Sterilization is the killing or removal of all micro-organisms on a transmission medium. A disinfectant is a preparation used to kill micro-organisms on a transmission medium so that the disinfection or sterilization requirement is met. The three definitions are taken from the 2002 edition of the Technical Standard for Disinfection.

An object surface means the general surfaces of places such as schools, childcare institutions, public places and homes, together with walls and floors. A note lists everyday items whose surfaces are covered: tables and chairs, bedside cabinets, sanitary fittings, door and window handles, stair rails, bus seats and grab handles, and children's toys.

A disinfection wet wipe is a wet wipe carried on non-woven fabric, textile, wood pulp composite, wood pulp paper or similar material, to which production water, a disinfectant and other auxiliary ingredients are added in suitable quantity, and which disinfects, cleans and kills germs on the object it treats, such as the hands, the skin or an object surface.

The killing log value is the reduction in the number of micro-organisms between before and after disinfection when that number is expressed as a logarithm; the definition is taken from the 2002 edition of the Technical Standard for Disinfection.

4 Product classification

By the object they are used on, disinfection wet wipes fall into wipes for the human body and wipes for object surfaces.

5.1 General requirements and raw materials

The general requirements for disinfection wet wipes follow GB/T 27728.1.

A wipe for the human body does not use recovered or waste material as its carrier. The disinfectant used in any disinfection wet wipe is of non-industrial grade, except where no non-industrial grade exists; the disinfectant of a wipe for the human body meets GB 27951 and the disinfectant of a wipe for object surfaces meets GB 27952. Substances prohibited in a disinfectant follow GB 38850.

5.2.2 Inherent quality

Table 1 fixes the inherent quality of a wipe for the human body: liquid content not less than 1.7 times; pH value 3.5 to 8.5; lead not more than 10 mg/kg, arsenic not more than 2.0 mg/kg, cadmium not more than 5.0 mg/kg and mercury not more than 1.0 mg/kg; methanol, benzene, toluene and xylene each not more than 20 mg/kg; migratable fluorescent substances absent; formaldehyde not more than 75.0 mg/kg; methylisothiazolinone and methylchloroisothiazolinone not detected; the sum of dibutyl phthalate, benzyl butyl phthalate and di(2-ethylhexyl) phthalate not more than 0.001 2 %; and acrylamide not more than 0.1 mg/kg. Two footnotes state that liquid content is assessed only on a disinfection wet wipe made from non-woven fabric, and that where the package label or the instructions carry a declared value the pH lies within 1.0 unit of the declared centre value.

Table 2 fixes the inherent quality of a wipe for object surfaces. Liquid content, the four heavy metals, methanol, benzene, toluene, xylene, migratable fluorescent substances and formaldehyde carry the same limits as in Table 1. Metal corrosivity is added: practically no corrosion on stainless steel, and practically no corrosion or slight corrosion on carbon steel, aluminium and copper. Two footnotes state that liquid content is assessed only on a wipe made from non-woven fabric, and that metal corrosivity is assessed only on a wipe used on metal object surfaces, a wipe intended for a specific metal surface being assessed on that material alone.

5.2.3 Microbiological indicators

Table 3 fixes the microbial contamination indicators: total bacterial colony count not more than 20 CFU/g; coliforms not detected; the pyogenic pathogens Pseudomonas aeruginosa, Staphylococcus aureus and haemolytic streptococci not detected; total fungal colony count not detected.

A disinfection wet wipe is tested against the micro-organisms matching the field of use and the class of micro-organism declared on its label or in its instructions, and where the label claims action against other specified micro-organisms the matching killing test is also run.

Table 4 fixes the microbicidal indicators against the object of disinfection. For

Staphylococcus aureus the test is compulsory for the hands, the skin and object surfaces. For Escherichia coli it is compulsory for the hands and object surfaces and optional for the skin. For Pseudomonas aeruginosa it is compulsory for the skin and optional for the hands and object surfaces. For Candida albicans and Aspergillus niger it is optional for all three objects. The killing log value for the three bacteria is not less than 5.0 by the suspension method and not less than 3.0 by the carrier method; for the two fungi it is not less than 4.0 by the suspension method and not less than 3.0 by the carrier method. Notes state that the suspension method and the carrier method are alternatives, and that a product labelled as killing pathogenic fungi is tested against Candida albicans and Aspergillus niger.

5.2.4 Active ingredient content, stability and toxicology

The active ingredient content matches the content declared on the label or in the instructions and lies within 10 % of the declared centre value; for a chlorine dioxide, peroxide or chlorine-releasing disinfectant it lies within 15 % of the declared centre value. Table 5 sets limits in grams per litre on restricted substances in the expressed liquid of a wipe for the human body: chlorhexidine gluconate or chlorhexidine acetate not more than 45; 2,4,4'-trichloro-2'-hydroxydiphenyl ether not more than 20; benzalkonium bromide or benzalkonium chloride not more than 5; other substances restricted by the State to conform to the rules laid down for them.

A stability test is run before a new product first reaches the market and whenever the raw materials or the production process change substantially. The shelf life is not less than one year, and within it Table 6 requires a liquid content of not less than 1.7 times, a fall in active ingredient content of not more than 10 %, and microbicidal indicators meeting 5.2.3.2. A footnote makes the fall in active ingredient content and the microbicidal indicators alternatives, the microbicidal test being run when the fall in active ingredient content does not conform.

A toxicological test is run before a new product first reaches the market and whenever the raw materials or the production process change substantially. Table 7 fixes the indicators. The acute oral toxicity test is compulsory for the hands, the skin and object surfaces, with the result practically non-toxic. The single complete skin irritation test is compulsory for the skin and object surfaces and optional for the hands; the repeated complete skin irritation test is compulsory for the hands and optional for the skin and object surfaces; both results are no irritation or slight irritation. One mutagenicity test is compulsory for all three objects, with a negative result. The skin sensitization test is optional for all three, with no reaction or a very slight reaction. Footnotes state that a product touching the skin in use takes the single test, that a product used repeatedly takes the repeated test which then replaces the single test, and that the gene mutation test and the chromosome aberration test are alternatives.

The wipe surface is clean and undamaged and carries no foreign matter and no stains.