Japan Hygiene Products Industry Association, Inc.

Voluntary Standards for Antibacterial Features

Japan Hygiene Products
Industry Association, Inc.

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Introduction

The Voluntary Standards for Antibacterial Features (the “Voluntary Standards”) define the antibacterial performance test methods, antibacterial performance standards, safety standards, and labeling standards in order to claim antibacterial effects of the antibacterial finished products produced by the Japan Hygiene Products Industry Association (“JHPIA”) members.

1. Objective

The objective for the Voluntary Standards is the provision of guidelines regarding antibacterial performance, safety and labeling to provide products to consumers with consistent antibacterial performance, and the education of proper usage, which enhances quality of life on a social scale.

2. Applicable Products

The Voluntary Standards apply to the hygiene products covered under JHPIA, such as disposable diapers, pantyliners, bandages, triangle bandages, T-shaped bands, bleached cotton, childbirth pads, masks, wet towels, wet tissues, cotton swabs, etc., that claim the antibacterial effects. The product definitions are indicated in Table 1.

Table 1. Applicable products

Applicable products	Definition
Disposable diapers	Used for urine and feces in excretory care
pantyliners	Used for vaginal discharges
bandages	Used over a wounded area or to anchor treatment patches.
Triangular cloth	A triangle cloth cut diagonally from one meter square cloth. Used as a first-aid measure or head cover during manual labor.
T-shaped bands	Cloth with a string attached to side to fasten and protect the anus or genitals after an operation or childbirth when underwear cannot be worn.
Bleached cotton	Used to wrap around the abdomen after surgery or childbirth to protect and keep the area warm.
Childbirth pads	Used for discharges after childbirth.
Masks	Used to cover the mouth and nose to limit the entry of pollens and dust as well as to limit the spread of airborne droplets of coughing and sneezing.
Wet towels and wet tissues	Tissues and towels impregnated with chemical solution. Used to clean body parts.
Cotton swabs	Cotton wad is attached to one or both ends of a paper or plastic stem. Used to clean body parts.

3. Definition

The “antibacterial” in “antibacterial finished products” means “repression of bacterial growth on the surface of relevant products or sites (including the material).” However, mycophyta, such as mold and fungus, or viruses are not included.

4. Antibacterial Performance Standards for Products

A manufacturer of products with antibacterial finishing is required, by assigning a third party testing agency, either public or accredited by JHPIA, to perform the appropriate antibacterial performance tests (see Appendix) established by JHPIA in order to verify whether the products meet the antibacterial performance standards based on the type, usages, and antibacterial purpose.

The antibacterial performance tests and antibacterial performance standards established by a respective industry association may be added as the antibacterial performance tests and antibacterial performance standards established by JHPIA through the deliberation and approval of JHIPA’s Antibacterial Voluntary Standards Sub-committee of the Technical Committee and The Board of Directors.

5. Safety Standards for Products

A manufacturer or a sales company of products with antibacterial finishing is required to verify product safety based on its own safety data or the data obtained from the manufacturer of the antibacterial agent used in the process. If the data obtained from the manufacturer of the antibacterial agent is inadequate, the product manufacturer is required to verify the product safety by an appropriate test method based on types of usage.

6. Labeling Standards

6.1. Labeling Items

A manufacturer or a sales company of products with antibacterial finishing is required to perform antibacterial performance tests established by JHPIA to meet antibacterial performance standards. The items below must be included in the labeling associated with JHPIA standards.

(1) A statement that the products meet the voluntary standards for antibacterial features established by the Japan Hygiene Products Industry Association, or the antibacterial mark established by the Japan Hygiene Products Industry Association., or both. You may use the acronym “JHPIA” for the Japan Hygiene Products Industry Association.

The antibacterial mark established by JHPIA

(2) The type of antibacterial agents used in the product.
Classification such as organic, inorganic, or natural organic material, or a specific name of the material must be included. It is preferable to use terms that the consumer can easily understand.

Examples: organic antibacterial agent, inorganic antibacterial agent, alcohol-type antibacterial agent, quaternary ammonium salt, chlorhexidine gluconate, benzalkonium chloride, chitosan, catechin, silver, etc.

(3) The site where the antibacterial finishing is applied.
Use a figure, illustration, or statement, depending on the type and usage of the product that is easily understood by consumers. More than one method may be combined. No need to specify the site if antibacterial finishing is applied to the entire product (except for the container). However, in the case where the site which consists of multiple materials, such as the absorbent materials in disposable diapers, the antibacterial finished materials shall be clearly stated.

Examples: Cotton swab — cotton wad surface
Disposable diaper — superabsorbent polymer*
* In the case of only the superabsorbent polymer in the absorbent materials is antibacterial finished. When absorbent paper and superabsorbent polymer are antibacterial finished, it shall be stated as "Absorbent paper and suberabsorbent polymer."
Mask — inner filter

(4) Necessary cautions on usage regarding the antibacterial agent used or antibacterial finishing site.

Examples:
- Avoid prolonged usage.
- Store it in a sanitary place after the package is opened.
- Consult a physician if abnormality is discovered on the skin.

Note: These are examples, thus the cautionary wordings may not necessarily be the same, however, manufacturers shall place cautions on their own responsibility, in consideration of information, such as usage, antibacterial finished sites, safety data and findings.

(5) The following contents must be included on the labeling to avoid consumer misunderstanding.
- Bacterial growth is suppressed on the surface of the antibacterial finishing site.
- It cannot suppress all types of bacteria.

6.2. Labeling Methods

Various methods of labeling are allowed, such as the listing of labeling items in a table, or the use of illustration. If a diagram or illustration is used, it must expressly state whether it meets the Voluntary Standards for Antibacterial Features.

Examples of labeling are listed below:

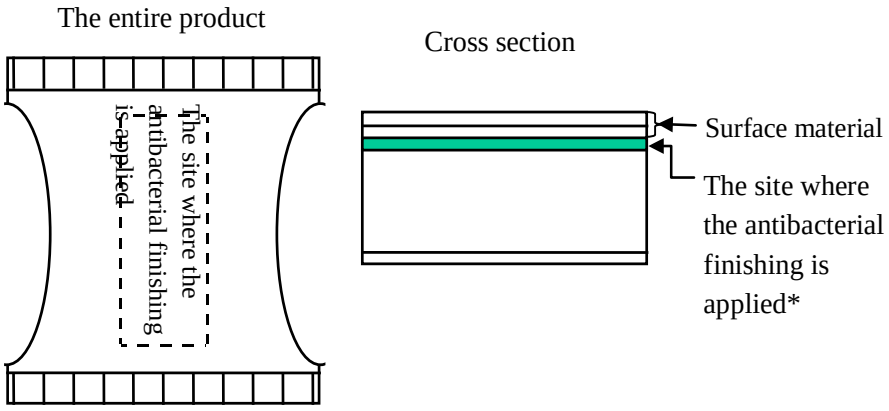
Labeling Example

i) The listing of labeling items in a table

Type of antibacterial agent	Organic antibacterial agent
Site where antibacterial finishing is applied	On the surface material
Cautions on usage	• Avoid prolonged usage. • Store in a sanitary place after the package has been opened. • Consult a physician if any abnormality is discovered on the skin.

Note: These are examples, thus the cautionary wordings may not necessarily be the same, however, manufacturers shall place cautions on their own responsibility, in consideration of information, such as usage, antibacterial finished sites, safety data and findings.

ii) The relevance is expressed using a figure. (In case of a disposable diaper)



*The labeling meets the Voluntary Standards for Antibacterial Features.

Antibacterial finished site: lower part of surface material

Antibacterial agent: organic antibacterial agent

Note: This applies when the surface material site consists of a single material.

If the labeling space on a package is limited to less than 50 cm^2, or a space cannot be secured for labeling on antibacterial finishing because of other labeling requirements by law, labeling items of products with antibacterial finishing may be abbreviated. However, legally required labeling items (such as items required by household products quality labeling law) must be listed.

7. Labeling Secondary Antibacterial Effects

If secondary antibacterial effects, such as deodorization or odor suppression, are included in the labeling, they must be verified with a scientifically valid and suitable method for product usage established by their own or a respective industry association, and documentation must be prepared for disclosure if requested.

8. Implementation

Once a year, JHPIA shall request its member companies to submit a list of products with an antibacterial claim, as well as randomly select such antibacterial products and request the manufacturers to submit data.

Supplementary provision:

Changes to labeling due to a revision of The Voluntary Standards take effect on the day of the revision. Production with new labeling shall be carried out within two years of the implementation of the revision. Within the two year allowance, member companies shall make an effort to change labeling within a reasonable period of time and sell out the products with old labeling distributed to retailers as soon as possible.

Appendix Antibacterial Performance Tests, Standards and Scope of Antibacterial Claim

The table below shows antibacterial performance test methods, antibacterial performance standards and the scope of antibacterial claim established by JHPIA.

Product Category		Test method and condition					Antibacterial Performance Standard	Scope of Antibacterial Claim
		Test Method	Contaminated material	Stand-ing Time	Passage Condition	Tested Bacteria		
Fiber products/sites (including nonwovens and cotton wads of swabs)	Disposable diapers (without super absorbent polymer)	Comply with JIS L1902 Muslin #3 with standard bleaching may be used as an unprocessed product.	1/20 NB[1)] 0.2 mL/0.4g	18 hrs.	F[2)] ≧1.5	• Staphylococcus aureus • Escherichia coli	Antibacterial activity value[5)], more than 2.0	Antibacterial effect while worn. However, the effect is excluded after contaminated with feces and/or urine.
	pantyliners		1/20 NB 0.2 mL/0.4g		F ≧1.5	• Staphylococcus aureus • Escherichia coli	Antibacterial activity value, more than 2.0	Antibacterial effect while worn. However, the effect is excluded after contaminated with body fluid such as vaginal discharges.
	bandages, triangular cloth, T-shaped bands, bleached cotton		1/20 NB 0.2 mL/0.4g		F ≧1.5	• Staphylococcus aureus • Escherichia coli	Antibacterial activity value, more than 2.0	Antibacterial effect while used. However, the effect is excluded after contaminated with substances such as body fluid and blood.
	Childbirth pads		1/20 NB 0.2 mL/0.4g		F ≧1.5	• Staphylococcus aureus • Escherichia coli	Antibacterial activity value, more than 2.0	Antibacterial effect while worn. However, the effect is excluded after contaminated with substances such as vaginal discharges, blood and body fluid.
	Masks		1/20 NB 0.2 mL/0.4g		F ≧1.5	• Staphylococcus aureus • Escherichia coli	Antibacterial activity value, more than 2.0	Antibacterial effect while used. However, the effect on viruses is excluded.
	Wet towels and wet tissues		1/500 NB 0.2 mL/0.4g		F ≧ 0.5	• Staphylococcus aureus • Escherichia coli	Sterilization activity value[5)], more than 0.	Antibacterial effect until the package is opened.
	Cotton swabs[2)]		More than 1/500 NB 0.2 mL/0.4g		F ≧ 0.5	• Staphylococcus aureus • Escherichia coli	Sterilization activity value, more than 0.	Antibacterial effect until the package is opened.
Super-absorbent polymer	Disposable diapers	Determination of antibacterial activity of superabsorbent polymer[3)]	Artificial urine	18 hrs. (36±2 ℃)	F ≧2.0	• Staphylococcus aureus • Escherichia coli	Antibacterial activity value[5)], more than 2.0	Antibacterial effect after urine is absorbed.

If a product is washable and expected to be used multiple times, the retention of its antibacterial performance must be verified by a washing endurance test under hypothesized washing conditions and repeated numerous times.

1) NB: Nutrient culture media
2) The cotton wad of a swab is removed from the stem and used as a test sample because there are products where only the cotton wad surface is treated with antibacterial finishing.
3) Established by Japan Hygiene Products Industry Association and Japan Superabsorbent Polymer Industrial Association in June 2017.
4) Refer to the Determination of antibacterial activity of superabsorbent polymer[3)].
5) Refer to the following calculation formulas (1)~(4) for F (growth value), antibacterial activity value and sterilization activity value.

i) **For fiber products or their parts (including nonwoven fabrics and cotton wads of swab**s)

F (growth value) $F = \log C_t - \log C_0$ ·····(1)

Antibacterial activity value $A = (\log C_t - \log C_0) - (\log T_t - \log T_0)$ ·····(2)

Sterilization activity value $A - F = \{ (\log C_t - \log C_0) - (\log T_t - \log T_0) \} - (\log C_t - \log C_0)$ ·····(3)

For the above calculation formulas, apply the corresponding values obtained as below.

$\log C_t$: The common logarithm of arithmetic mean of viable bacteria count or the amount of ATP, from 3 control specimens after a cultivation for 18~24 hours.

$\log C_0$: The common logarithm of arithmetic mean of viable bacteria count or the amount of ATP, from 3 control specimens immediately after an inoculation.

$\log T_t$: The common logarithm of arithmetic mean of viable bacteria count or the amount of ATP, from 3 testing specimens after a cultivation for 18~24 hours.

$\log T_0$: The common logarithm of arithmetic mean of viable bacteria count or the amount of ATP, from 3 testing specimens immediately after an inoculation.

(In the case of $\log C_0 > \log T_0$, replace $\log T_0$ with $\log C_0$.)

Note: These conform with 8.1.5.1 and 8.1.5.2. of JIS L1902 :2015.

ii) For superabsorbent polymer

Antibacterial activity value $A = A_c - A_i$ ·····(4)

For the above calculation formula, apply the corresponding values obtained as below.

A_c : Average of the common logarithm of viable bacteria count, from 3 control specimens after a cultivation for 18 hours.

A_i : Average of the common logarithm of viable bacteria count, from 3 testing specimens after a cultivation for 18 hours.

Note: These conform with the Determination of antibacterial activity of superabsorbent polymer (established by Japan Hygiene Products Industry Association and Japan Superabsorbent Polymer Industrial Association in June 2017).

Explanation of Antibacterial Effect Test Methods and Standard Value

This section explains the reasons that the Japan Hygiene Products Industry Association established The Voluntary Standards. It shall not be construed as a part of the standards.

1. Original standards and history of revisions

In December 1998, the Japan Hygiene Products Industry Association ("JHPIA") received "The Report of the Roundtable Conference for Household Products with Processed New Features (published by the former Ministry of International Industry and Trade)." The report stated that products with antibacterial finishing were sold without clear standards and that respective industry group needed to establish voluntary standards. In response, JHPIA formed an Antibacterial Working Group under the Legal Affairs Committee, and in April 1, 2001, it established the Voluntary Standards for Antibacterial Features for hygiene products (disposable diapers, bandages and childbirth pads) that are covered under JHPIA at the time.

Thereafter, the Japan Clean Paper and Cotton Industry Association (in 2001), and the National Mask Industry Association (in 2005) joined JHPIA, which increased the covered product base. In addition, the industry expanded the scope and variety of products with antibacterial finishing. Because of this, respective antibacterial performance tests for each product category needed to be established. Accordingly, at the revision of April 2008, JHPIA adopted the Determination of antibacterial activity and efficacy of textile products (JIS L1902) as its antibacterial performance test method, and established the acceptance criteria for each product category or site, as well as the labeling method and its implementation. In October 2010, in accordance with the 2008 revision of JIS L1902, the calculation methods for bacteriostasis activity value were revised.

Subsequently, to respond to the increasing need for test methods to evaluate the antibacterial efficacy of absorbent polymer used in products such as disposable diapers, the Project for development of determination of antibacterial activity of superabsorbent polymer was launched in collaboration with Japan Superabsorbent Polymer Industrial Association. Under the guidance of Professor Hiroki Kourai (Professor Emeritus, Tokushima University), the project team developed the "Determination of antibacterial activity of superabsorbent polymer," and completed the test methods in 2017. Upon completion, the test methods were added to the Voluntary Standards (see Appendix), and the changes were also made to conform to the 2015 revision of JIS L1902, replacing the term "bacteriostasis activity value" with "antibacterial activity value" to reflect the change/deletion of terms, such as "bacteriostasis activity value" and "sterilization activity value." The deleted "sterilization activity value" was also defined by calculation formulas.

2. Applicable products

Applicable products are the products covered under JHPIA, excluding drug, medical device, quasi drug, and cosmetic products that are subject to the Pharmaceutical Affairs Act. Specifically, cotton swabs, disposable diapers, pantyliners, bandages, triangle bandages, T-shaped bands, bleached cotton, childbirth pads, wet tissues, wet towels, and masks are subject to the standards. Feminine napkins that are subject to the Pharmaceutical Affairs Act, and sweat control pads that are not covered under JHPIA are excluded.

There is an assumption that there will be new products with antibacterial claim in the future. Therefore, the language in the standards includes "….masks, etc." to cover expansion of the product base.

3. Definition of Antibacterial Features

"Suppression of bacterial growth on the surface of a product (including the material)" provided in "The Report of the Roundtable Conference for Household Products with Processed New Features" was applied for the definition of antibacterial features. The term "surface" does not mean the "top face" or "back face" of a product. Instead it means the "surface" in the condensed matter physics realm, where the material (solid substance) and air (gaseous matter) interface on which microorganisms may contact.

4. Antibacterial Performance Tests and Standards

4.1 Antibacterial Performance Tests, Antibacterial Performance Standards, and the Scope of Antibacterial claim

The main materials covered under JHPIA are fiber products, such as nonwoven fabric, cotton cloth and pulp, as well as superabsorbent polymer.

Test methods for evaluating antibacterial effects on fiber products, such as nonwoven fabric, cotton cloth and pulp, have been established in JIS L1902 "Determination of antibacterial activity and efficacy of textile products," thus JHPIA applied the method without any change. Meanwhile, since there was no public testing method to evaluate antibacterial effects on superabsorbent polymer, JHPIA developed the "Determination of antibacterial effect of superabsorbent polymer" jointly with Japan Superabsorbent Polymer Industrial Association under the guidance of Professor Hiroki Kourai (Professor Emeritus, Tokushima University).

4.2 Antibacterial Performance Tests and Standards for Intended Antibacterial Effects for Products in Use

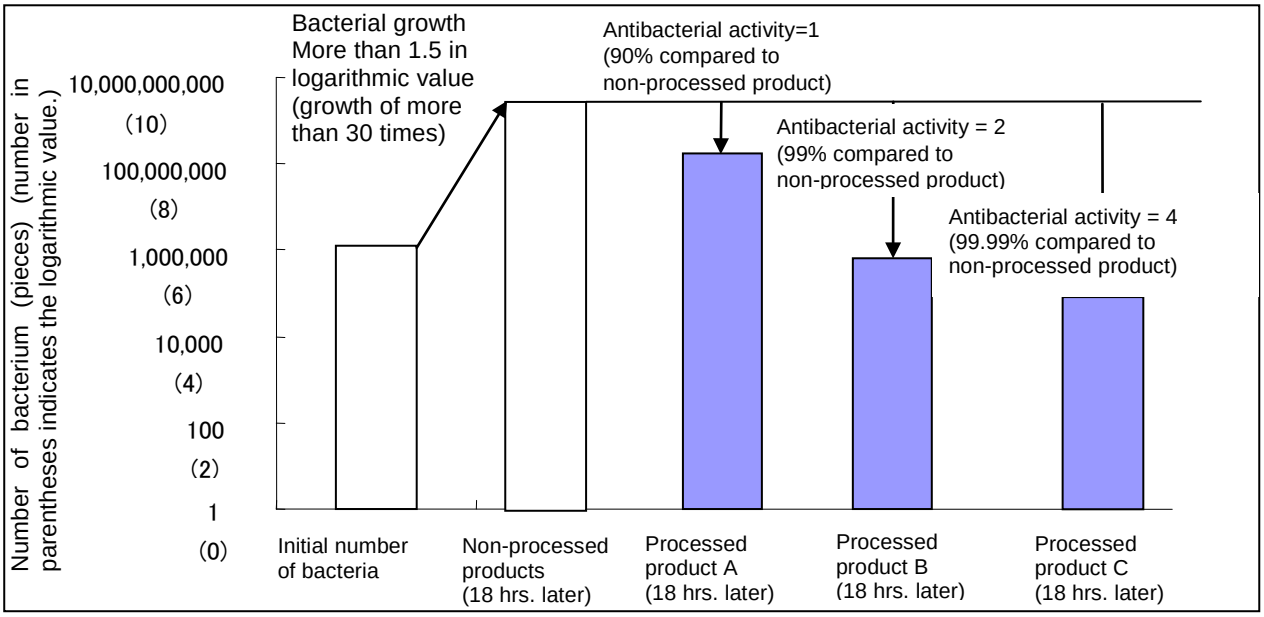
The antibacterial performance standard is more than 2.0 of antibacterial activity value for products with intended antibacterial effects, such as disposable diapers, pantyliners, bandages, triangle bandages, T-shaped bands, bleached cotton, childbirth pads, masks, etc. Antibacterial activity value is indicated by the differential logarithmic value of viable bacteria between non-processed products and processed products in a test where a sample processed with antibacterial finishing and a non-processed sample were inoculated with bacteria, and viable bacteria were measured after eighteen hours of culturing (Refer to Figure 1). It does not mean, however, that bacteria don't grow.

These products are designed to be in contact with human body for long periods of time. Therefore, it is assumed that bacteria transferred from the skin or external environment will grow on the product in use. Based on the antibacterial standard (JIS L1902) for fibers with antibacterial finishing, the standard value of antibacterial activity value is more than 2.0, which means the growth of the bacteria transferred from the skin or external environment is suppressed more than 99% (less than 1% transferred) when compared to a non-processed product. This is considered to be significant and beneficial to the consumers of this category of products.

Therefore, JHIPA set the antibacterial performance standard at more than 2.0 on antibacterial activity value

with the assumption of in-use scenario. In Figure 1, products with antibacterial finishing A fail while products with antibacterial finishing B and C pass the test.

Figure 1　Conceptual diagram for antibacterial activity value



(Products with antibacterial finishing A: Fail, Products with antibacterial finishing B and C: Pass)

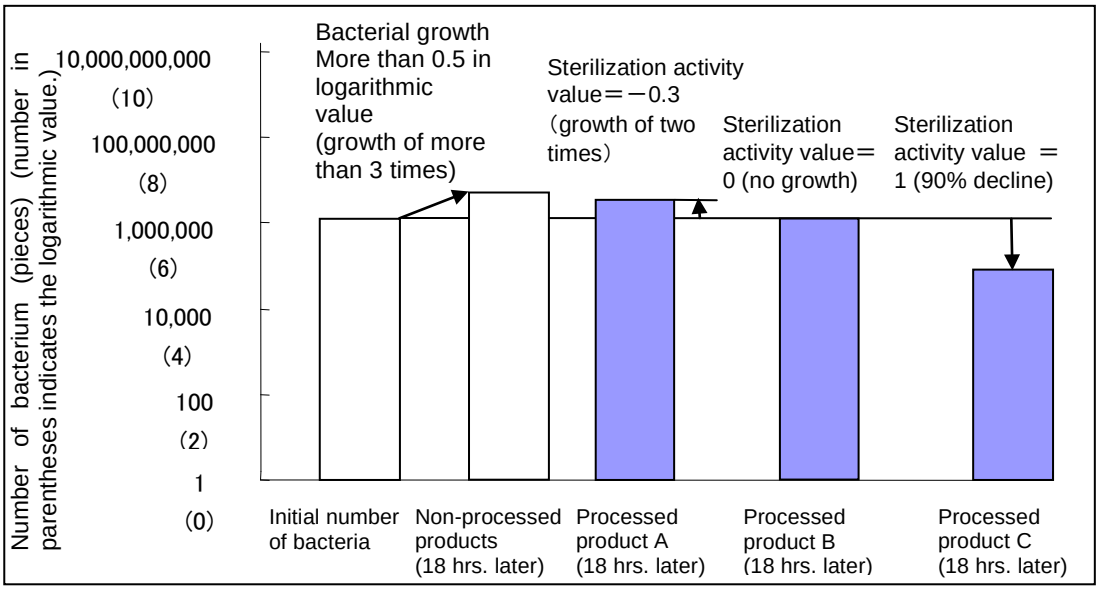
4.3　Antibacterial Performance Tests and Standards for Intended Antibacterial Effects for Products Before Use

In the antibacterial performance standard, the sterilization activity value is set to be more than zero (0) for products with intended antibacterial effects before use, such as wet tissues and cotton swabs.　Sterilization activity is indicated by the differential logarithmic value of viable bacteria on the processed products compared to the logarithmic value of the number of inoculated bacteria in a test where a sample processed with antibacterial finishing was inoculated with bacteria, and viable bacteria were measured after eighteen hours of culturing.　Sterilization activity value 1 indicates a bacteria reduction of 90% (Refer to Figure 2).

Wet tissues and cotton swabs are used for a short period of time and discarded before any bacteria grows even when they make contact with the product in use.　Consumer benefits of antibacterial effects in use are not meaningful.　Therefore, the antibacterial features of these product groups are intended to be effective before a package is opened.　The antibacterial standards for this category assume minimal contamination before a package is opened. The contamination during a test is set to be 1/500 NB or more and the sterilization activity value is set to be zero (0).

In Figure 2, products with antibacterial finishing A fail while products with antibacterial finishing B and C pass the test.

Figure 2　Conceptual diagram for sterilization activity value



(Products with antibacterial finishing A: Fail, Products with antibacterial finishing B and C: Pass)

4.4 Antibacterial Performance Tests and Standards for Superabsorbent Polymer

Disposable diaper is composed of three parts: "surface material" which contacts with skin, "absorbent materials" which consists of paper, pulp and superabsorbent polymer to absorb urine, and "waterproof material" which serves as a diaper cover. Superabsorbent polymer with high absorption capacity and water retention capacity contributes to making disposable diapers compact while preventing leakage and flow back of urine to skin.

Since the main functions of superabsorbent polymer are absorption and retention of urine, the antibacterial effect of superabsorbent polymer has been defined as after urine is absorbed.

5. Q&A for Antibacterial Performance Tests and Standards

Q1. If only the same effects as the secondary antibacterial effects (i.e. odor elimination, or deodorization) are claimed, are the products subject to The Voluntary Standards?

A1. If odor elimination or deodorization is achieved by any other means than antibacterial effects, and an antibacterial claim is not made, then it is not subject to The Voluntary Standards.

Q2. Are bacterial control effects (SEIKIN*) subject to the Voluntary Standards?

A2. The Voluntary Standards are applied to products with antibacterial finishing. The control of a wider range of bacteria is not subject to The Voluntary Standards.

(* *The bacterial control effects (SEIKIN) covers a wider range of bacteria than the antibacterial effects (KOKIN) that are subject under this JHPIA Voluntary Standards.)*

Q3. What are the specific items in the Safety Standards?

A3. The Fiber Evaluation Technical Committee and Antibacterial Products Technical Committee list the following safety test items for antibacterial agents: acute toxicity via the oral route, a primary skin stimulation test, a mutagenicity test, and a skin sensitization test. Product safety items include an elution test and a skin patch test.

Q4. "Labeling based on JHIPA standards" is required on the labeling for disposable diapers. Can the antibacterial labeling items be integrated into the required labeling for disposable diapers?

A4. You may integrate both requirements into one label. If it is a product with antibacterial finishing, then base the labeling on the "JHPIA Standards and the Voluntary Standards" including items 2, 3, 4 of Section 6 of the Voluntary Standards for Antibacterial Features.

Q5. Is it required to label products with an antibacterial claim based on the "JHPIA Voluntary Standards?"

A5. It is not required, but for the purpose of the dissemination of the Voluntary Standards, it is desirable to include labeling that meets the Voluntary Standards for Antibacterial Features if a product claims antibacterial effects.

Q6. If an antibacterial claim solicits too much consumer expectations, should any disclaimer be included in labeling?

A6. It is impractical to test all types of bacteria. The Voluntary Standards provide testing of only the major types of bacteria (two types). It's not possible to guarantee antibacterial effects for all types of bacteria in the environment. Therefore, if excessive expectations by the consumer are anticipated for a product with an antibacterial claim, the manufacturer or pertinent industry association may, at their own risk, wish to consider including a disclaimer (such as, "This product does not provide antibacterial effects on all types of bacteria").

Q7. We use an antibacterial agent that does not meet the antibacterial performance standard provided by the Voluntary Standards. May we claim that an "antibacterial agent" is used? We do not claim any "antibacterial effects."

A7. Despite the substandard antibacterial performance, a product label that states "antibacterial agent is used (or blended)" or "typical antibacterial agent such as silver is used (or blended)" could mislead consumers in believing that the product has antibacterial effects. Therefore, it is not desirable to make similar claims (such as "antibacterial agent is used (or blended)" or "typical antibacterial agent such as silver is used (or blended)," even though the product with substandard antibacterial performance is not claiming antibacterial effects.

Q8. If "antibacterial deodorizing effects" are claimed, are the Voluntary Standards applied?

A8. Because an antibacterial deodorizing effect is a secondary effect of antibacterial features, the Voluntary Standards are not directly applicable. Any secondary effects should be validated by a

scientific method separately established by the manufacturer of the product with antibacterial finishing or a pertinent industry association based on its usage. It is necessary to prepare documents for disclosure if requested. (Refer to Section 7. Labeling on Secondary Antibacterial Effects)

Q9. What kind of additional antibacterial performance tests could be conducted to provide "the antibacterial performance tests and antibacterial performance standards newly established by each industry association" in the Antibacterial Performance Standards?

A9. The new antibacterial performance tests could include those to evaluate "antibacterial effects of materials other than superabsorbent polymer after urination onto disposable diapers" or "antibacterial effects after contaminated with body fluid such as vaginal discharges onto pantyliners."

Q10. In Section 7, Labeling on Secondary Antibacterial Effects, it states, "They must be verified with a scientifically valid and suitable method for product usage established by their own or a respective industry association." What is an appropriate verification method?

A10. Generally speaking, appropriate methods cannot be specified because they vary by individual cases. As an example, you can test and measure the difference of a secondary effect by inoculating appropriate testing bacteria and artificially introducing contamination (or actual contamination) on a non-processed product and processed product with antibacterial finishing, or by comparing the two types of samples after actual use.

Q11. Can we make an antibacterial claim based on our own antibacterial tests and standards?

A11. When you make an antibacterial claim of products or sites/materials which the Voluntary Standards for Antibacterial Features can apply, we think it desirable that the Antibacterial Performance Tests/Standards specified in the Voluntary Standards be applied.