

## Labeling and Terminology Provisions

### 1. Objective

These detailed rules **define the terms related to** antibacterial products, antifungal products, antiviral products, **industrial sterilization coating materials**, antibacterial agents, antifungal agents, antiviral agents, **and industrial sterilization coating agents** (hereinafter, these **eight** items are collectively referred to as “products, etc.”), **as well as** stipulate the standards for labeling for **such products** to **provide their users with necessary information**.

### 2. Scope

The “**Voluntary Specifications for Quality and Safety**” shall apply.

### 3. Definitions of Terms

- (1) Antibacterial  
Refers to suppression of the proliferation of bacteria on the surface of a product.
- (2) Antifungal  
Refers to suppression of the growth of fungi such as molds.
- (3) Antiviral  
Refers to decrease of the number of specific viruses on a product.
- (4) **Sterilization (Definition in JIS Z 2811)**  
Refers to a decrease of the viable count of an object.
- (5) **Industrial sterilization coating**  
Refers to the name of a category used for coating liquids and paints applied to decrease the viable count of an object.
- (6) Antibacterial agent  
Refers to an agent (or material) having an antibacterial function.  
Distinguishing between agents and materials  
All antibacterial agents sold by manufacturers of antibacterial agents shall be handled as “agents,” whereas antibacterial master batches, antibacterial stainless steel, etc. for secondary products shall be handled as “materials.” **In addition, antibacterial (and/or antiviral) coating liquids using antibacterial and/or antiviral agents shall be handled as “coating materials.”** Under these provisions, the term agents is used to represent both types.
- (7) Antifungal agent  
Refers to an agent having an antifungal function.
- (8) Antivirus agent  
Refers to **an agent (substance) that brings out** an antiviral function.
- (9) **Industrial sterilization coating agent**  
Refers to **an agent (substance) that brings out the function of an industrial sterilization coating.**
- (10) Inorganic antibacterial agent containing silver, etc.  
Refers to an antibacterial agent prepared by impregnating a metal such as silver, copper, or zinc, an inorganic compound thereof, or a mixture thereof, in an inorganic compound.
- (11) Organic antibacterial agent  
Refers to a synthetic organic antibacterial agent and natural organic antibacterial agent.
- (12) Inorganic antifungal agent  
Refers to an antifungal agent made by impregnating an inorganic compound with metals such as silver, copper, and zinc, inorganic compounds of such metals, and their mixtures.
- (13) Organic antifungal agent  
Refers to a synthetic organic antifungal agent and natural organic antifungal agent.
- (14) Inorganic antiviral agent

Refers to an antiviral agent made by impregnating an inorganic compound with metals such as silver, copper, and zinc, inorganic compounds of such metals, and their mixtures.

- (15) Organic antiviral agent  
Refers to a synthetic organic antiviral agent and natural organic antiviral agent.
- (16) Inorganic industrial sterilization coating agent  
Refers to an industrial sterilization coating agent made by impregnating an inorganic compound with metals such as silver, copper, and zinc, inorganic compounds of such metals, and their mixtures.
- (17) Organic industrial sterilization coating agent  
Refers to a synthetic organic industrial sterilization coating agent and natural organic industrial sterilization coating agent.
- (18) Organic-inorganic mixed antibacterial agent  
Refers to a synthetic organic antibacterial agent, natural organic antibacterial agent, and a mixture of these antibacterial agents and inorganic bacterial agent
- (19) Organic-inorganic mixed antifungal agent  
Refers to a synthetic organic antifungal agent, natural organic antifungal agent, and a mixture of these antifungal agents and inorganic antifungal agent
- (20) Organic-inorganic mixed antiviral agent  
Refers to a synthetic organic antiviral agent, natural organic antiviral agent, and a mixture of these antiviral agents and inorganic antiviral agent
- (21) Organic-inorganic mixed industrial sterilization coating agent  
Refers to a synthetic organic industrial sterilization coating agent, natural organic industrial sterilization coating agent, and a mixture of a synthetic or natural organic industrial sterilization coating agent and an inorganic industrial sterilization coating agent.
- (22) Antibacterial metal  
Refers to a metal material having an antibacterial function.
- (23) Antiviral metal  
Refers to a metal material having an antiviral function.
- (24) Antibacterial product  
Refers to a product undergoing antibacterial treatment by the use of antibacterial agents with the objective of providing antibacterial function, whether it is a finished product or an intermediate product. However, antibacterial metals shall be handled as antibacterial products.
- (25) Antifungal product  
Refers to a product undergoing antifungal treatment, whether it is a finished product or an intermediate product.
- (26) Antiviral product  
Refers to a product undergoing antiviral treatment, whether it is a finished product or an intermediate product.
- (27) Industrial sterilization coating material  
Refers to a coating liquid and paint applied to decrease the bacterial count of an object, which forms a film on the object by applying them. Objects coated with this material are not included in this product.
- (28) Equivalent antibacterial products  
Refers to antibacterial products, etc. that share the same material, manufacturing process, and antibacterial agent specifications (antibacterial agent used, treatment method, range of amount added, etc.) but differ only in terms of secondary factors such as shape.
- (29) Equivalent antifungal products  
Refers to antifungal products, etc. that share the same material, manufacturing process, and antifungal agent specifications (antifungal agent used, treatment method, range of amount added, etc.), but differ only in terms of secondary factors such as shape.
- (30) Equivalent antiviral products  
Refers to antiviral products, etc. that share the same material, manufacturing process, and antiviral agent specifications (antiviral agent used, treatment method, range of amount added, etc.) but differ only in terms of secondary factors such as shape.
- (31) Equivalent industrial sterilization coating material

Refers to an industrial sterilization coating material that shares the same material, manufacturing process, and industrial sterilization coating agent specifications (industrial sterilization coating agent used, range of amount added, manufacturing process, etc.), but differs only in terms of other components that do not affect the industrial sterilization coating function.

- (32) Chemical substance  
Article 2-1 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as “Chemical Substances Control Act”) as shown below shall be observed.  
Refers to a compound obtained by causing a chemical reaction on an element or compound (excluding radioactive substances and the products listed below).
- (i) Radioactive substances defined in Article 20 of the Atomic Energy Basic Law
  - (ii) Designated substances defined in Article 2-3 of the Poisonous and Deleterious Substances Control Law (1950 Law No. 303)
  - (iii) Stimulant drugs defined in Article 2-1 of the Stimulant Drug Control Law (1951 Law No. 252) and raw materials for stimulant drugs specified in Article 2-5
  - (iv) Narcotics defined in Article 2-1 of the Narcotic Control Law (1953 Law No. 14)
- (33) General chemical substance  
The following chemical substances defined in Article 2-7 of Chemical Substances Control Act (excluding priority assessment chemical substances, monitoring chemical substances, class I specified chemical substances, and class II specified chemical substances):
- (i) Chemical substances listed in the list of existing chemical substances
  - (ii) Newly announced chemical substances
  - (iii) Previous class II and III monitoring chemical substances  
\* 1 – 3 exclude the substances designated as priority assessment chemical substances, etc.
  - (iv) Chemical substances whose designation as priority assessment chemical substance has been canceled
- (34) Safety test concentration  
Refers to the “concentration of an antibacterial, antifungal, antiviral, or industrial sterilization coating agent” used in the safety test, which is calculated with such product (active ingredient) as the base value (based on 100% by weight).
- (35) Fungal resistance test  
Refers to a test for evaluating the resistance of an antifungal product to fungi.
- (36) Durability-tested product  
Refers to a product that underwent durability testing under the conditions specified for each product category.
- (37) Label, etc.  
Refers to a package box, label, instruction manual, etc. attached to products, etc.
- (38) Pamphlet, etc.  
Refers to all media stating the information on products, etc., including technical documents, catalogues, pamphlets, newspaper/magazine advertisements, TV commercial messages concerning products, etc.
- (39) Antibacterial activity value  
A value indicating the difference in the common logarithms of viable cell count after inoculation culture between the surface of non-antibacterial products and antibacterial products.
- (40) Antiviral activity  
A value indicating the difference in the common logarithms of viral infectivity after a specified virus inoculation time period, between the surface of non-antiviral products and antiviral products.
- (41) Repetitive reduction value (Evaluation of an industrial sterilization coating material)  
JS Z 2811 shall apply (A value indicating the difference in the common logarithms of viable count, between an uncoated test piece immediately after bacterial inoculation and a coated test piece that has undergone repetitive operation after four hours of inoculation).
- (42) Comparative repetitive reduction value (Evaluation of an industrial sterilization coating material)

A value indicating the difference in the common logarithms of viable count after four hours of inoculation, between an uncoated test piece that has undergone repetitive operation and a coated test piece that has undergone repetitive operation.

4. On Labeling and Terminology for Products, etc.  
For voluntarily registered product, etc., the following matters shall, as a rule, be indicated at an easily noticeable portion by the users on the label, etc. of the product, etc. For JIS-specified commodities, relevant provisions of the Industrial Standardization Act shall apply.
  - (1) Name of the manufacturer or vendor of the product, etc.
  - (2) Name and code number of the product, etc.
  - (3) To the manners of description and label application for the type of the antibacterial agent used, information on the antifungal agent used, and the information, treatment method, and treatment portion of the antiviral agent used, the separately formulated “SIAA Brand Mark Management and Operation Provisions” shall be applied.
  - (4) Mode of use for assuring the onset and persistence of the desired antibacterial, antifungal, or antiviral effect  
This item shall be described in handling instructions, cautions, etc.
  - (5) Antibacterial SIAA brand mark  
The antibacterial SIAA brand mark shall be accompanied by a statement of necessary matters selected out of the type, antibacterial treatment method, and treatment portion of the antibacterial agent, etc. used. The statement shall be given in a way that conforms to the separately formulated “SIAA Brand Mark Management and Operation Provisions.”
  - (6) Antifungal SIAA brand mark  
The antifungal SIAA brand mark shall be accompanied by a statement of necessary matters selected out of listing number of the Antifungal Agent Positive List, the method of antifungal treatment, antifungal treatment portion of the antifungal agent used. The statement shall be given in a way that conforms to the separately formulated “SIAA Brand Mark Management and Operation Provisions.”
  - (7) Antibacterial and antifungal SIAA brand mark  
The antibacterial and antifungal SIAA brand mark shall be accompanied by a statement of necessary matters selected out of SIAA antibacterial product number, SIAA antifungal product number, listing number of the Antifungal Agent Positive List, the method of antifungal treatment, antifungal treatment portion of the antifungal agent used. The statement shall be given in a way that conforms to the separately formulated “SIAA Brand Mark Management and Operation Provisions.”
  - (8) Antiviral SIAA brand mark  
The antiviral SIAA brand mark shall be accompanied by a statement of the necessary matters selected out of the type of the antiviral agent used, antiviral treatment method, and treatment portion. The statement shall be given in a way that conforms to the separately formulated “SIAA Brand Mark Management and Operation Provisions.”
  - (9) Sterilization coating SIAA brand mark  
The sterilization coating SIAA brand mark shall be accompanied by a statement of the necessary matters, such as the type of the industrial sterilization coating agent used. The statement shall be given in a way that conforms to the separately formulated “SIAA Brand Mark Management and Operation Provisions.”
5. On Labeling and Terminology for Pamphlets, etc. for Products, etc.
  - (1) The labeling and terminology shall conform to the labeling and terminology manual formulated by this society.
  - (2) The labeling and terminology, etc. that are used in Japan shall not be subject to legal regulations by the Pharmaceutical Affairs Law, Food Sanitation Law, Agricultural Chemicals Regulation Law, Poisonous and Deleterious Substances Control Law, Act against Unjustifiable Premiums and Misleading Representations and others. Additionally, ones that are used abroad shall not be subject to regulations by the relevant laws of the countries and

regions where products which are voluntarily registered with this society are manufactured and sold.

- (3) For JIS-specified commodities, the provisions of the **Japanese Industrial Standardization Act** shall apply.

6. On the Indication of the Substance Name(s) of Antibacterial Agent(s), **Antiviral Agent(s), or Industrial Sterilization Coating Agent(s)** Contained in Antibacterial Products, **Antiviral Products, or Industrial Sterilization Coating Materials**

Described below are provisions concerning how to indicate the substance name(s) and concentration(s) of the antibacterial agent(s), **antiviral agent(s), or industrial sterilization coating agent(s)** used in the antibacterial product, **antiviral product, or industrial sterilization coating material**, on sales promotion materials, etc. (\*1).

- (1) Indication of substance name(s)
  - 1) The substance name of the antibacterial agent, **antiviral agent, or industrial sterilization coating agent** used in the antibacterial product, **antiviral product, or industrial sterilization coating material** shall be indicated by its major classification name and middle classification name (system) according to “**Table 1.**” (\*2)
  - 2) When more than one antibacterial agent, **antiviral agent, or industrial sterilization coating agent** is contained, the substance names of all the antibacterial, **antiviral, or sterilizing** ingredients used shall be indicated by their major classification name and middle classification name (system). (\*3)
  - 3) In addition to the major classification name and middle classification name, chemical name, nonproprietary name, abbreviated name, etc. may be indicated as required.

- (2) Indication of concentrations used
  - 1) The concentration(s) of antibacterial, antiviral, or industrial sterilization coating agent(s) used in the antibacterial product, antiviral product, or industrial sterilization coating material shall not be indicated. (\*4)
- (3) Time of enforcement
  - 1) These rules concerning antibacterial products shall go into force for sales promotion materials, etc. generated on and after July 24, 2001. These rules concerning antiviral products shall go into force for sales promotion materials, etc. generated on and after April 1, 2019. These rules concerning industrial sterilization coating materials shall go into force for sales promotion materials, etc. generated on and after April 1, 2022.
  - 2) For already prepared materials concerning antibacterial products, their use will be permitted until September 2003, but will be no longer acceptable thereafter.

[Notes] \*1: Sales promotion materials, etc. are documents that are not attached to the body of the product, generated for the sake of an explanation of the product, such as catalogues, handbills, pamphlets, and SDS, and do not include labels, product instruction manuals, containers, etc. that are integral parts of the body of the product.

\*2: Labeling example; Synthetic organic antibacterial agent (alcohol-containing)  
Synthetic organic antiviral agent (alcohol-containing)

\*3: Labeling examples; Synthetic organic antibacterial agents (alcohol-containing, phenol-containing)  
Inorganic antibacterial agent (silver-containing)  
Synthetic organic antibacterial agent (alcohol-containing)  
Natural organic antibacterial agent (terpene-containing)  
Inorganic antiviral agent (silver-containing)

\*4: The antibacterial agents, antiviral agents, or industrial sterilization coating agents contained in the antibacterial product, antiviral product, or industrial sterilization coating material occur at various portions in the product depending on the intended use or treatment method for the product, accordingly, concentration labeling is sometimes inappropriate. Additionally, there is not always a correlation between the concentration and potency of antibacterial agents, antiviral agents, or industrial sterilization coating agents. Hence, when this occurs, a temporary rule is made not to indicate the concentration(s) of antibacterial agent(s), antiviral agent(s), and industrial sterilization coating agent(s) used in the product. A survey will take place on general concentration ranges by type of product, and the findings will be posted as reference information on the website of the society and elsewhere.

#### 7. On the Indication of the Active Ingredient Name(s) of Antifungal Agent(s) Contained in Antifungal Products

Described below are provisions concerning how to indicate the active ingredient name(s) and blending concentration(s) of the antifungal agent(s) used in the antifungal product on sales promotion materials, etc. (\*1).

- (1) Indication of active ingredient name(s)
  - 1) The active ingredient name of the antifungal agent used in the antifungal product shall be indicated by its nonproprietary name if one is used or by its major classification name selected according to "Classification of Antibacterial and Antifungal Agents." (\*2)
  - 2) If the chemical name of the active ingredient is used, the active ingredient name of the antifungal agent used in the antifungal product shall be indicated by its middle classification name selected according to "Table 1" or shall not be disclosed. (\*3)
- (2) Management of usage restrictions  
All the antifungal agents contained in antifungal products shall be "selected for use from among the antifungal agents included in the Antifungal Agent Positive List and satisfy the

conditions included in the information on the usage restriction of each antifungal agent,” and the maximum possible blending amount is specified as a safety requirement.

- [Notes] \*1: Sales promotion materials, etc. are documents that are not attached to the body of the product, generated for the sake of an explanation of the product, such as catalogues, handbills, pamphlets, and SDS, and do not include labels, product instruction manuals, containers, etc. that are integral parts of the body of the product.
- \*2: Labeling example; Synthetic organic antifungal agent
- \*3: Labeling examples; Alcohol-containing,  
Terpene-containing  
Not disclosed

**Table 1: Classification of Antibacterial, Antifungal, Antiviral, and Industrial Sterilization Coating Agents**

[Major classification]	[Middle classification]
Inorganic antibacterial agents Inorganic antifungal agents Inorganic antiviral agents <b>Inorganic industrial sterilization coating agents</b>	Silver-containing antibacterial agents Zinc-containing antibacterial agents Copper-containing antibacterial agents Other inorganic antibacterial agents (*1)
Synthetic organic antibacterial agents Synthetic organic antifungal agents Synthetic organic antiviral agents <b>Synthetic organic industrial sterilization coating agents</b>	Alcohol-containing synthetic organic antibacterial agents Phenol-containing synthetic organic antibacterial agents Aldehyde-containing synthetic organic antibacterial agents Carboxylic acid-containing synthetic organic antibacterial agents Ester-containing synthetic organic antibacterial agents Ether-containing synthetic organic antibacterial agents Nitrile-containing synthetic organic antibacterial agents Peroxide-containing synthetic organic antibacterial agents Halogen-containing synthetic organic antibacterial agents Pyridine/quinoline-containing synthetic organic antibacterial agents Triazine-containing synthetic organic antibacterial agents Isothiazolone-containing synthetic organic antibacterial agents Imidazole/thiazole-containing synthetic organic antibacterial agents Anilide-containing synthetic organic antibacterial agents Biguanide-containing synthetic organic antibacterial agents Disulfide-containing synthetic organic antibacterial agents Thiocarbamate-containing synthetic organic antibacterial agents Surfactant-containing synthetic organic antibacterial agents Organic metal-containing synthetic organic antibacterial agents Other synthetic organic antibacterial agents (*1)
Natural organic antibacterial agents Natural organic antifungal agents Natural organic antiviral agents <b>Natural organic industrial sterilization coating agents</b>	Terpene-containing natural organic antibacterial agents Carbohydrate-containing natural organic antibacterial agents Tropolone-containing natural organic antibacterial agents Ester-containing natural organic antibacterial agents Other natural organic antibacterial agents (*1)
Organic-inorganic mixed antibacterial agents Organic-inorganic mixed antifungal agents Organic-inorganic mixed antiviral agents <b>Organic-inorganic mixed industrial sterilization coating</b>	— (*2)



<b>agents</b>	
Photocatalytic antibacterial agents	Titanium oxide-containing photocatalytic antibacterial agents Other photocatalytic antibacterial agents (*1)
Antibacterial metals Antiviral metals	Antibacterial stainless steel Antibacterial alumite Antiviral stainless steel Antiviral alumite Other metals (* 1)

(Notes) \*1: If falling under the category of any other substance, the chemical name or nonproprietary name, etc. of the antibacterial or antiviral substance shall be specified in parentheses.

- \*2: For antibacterial, antiviral, **or industrial sterilization coating** agents, the middle classification names of the organic and inorganic antibacterial agents, the organic and inorganic antiviral agents, **and the organic and inorganic industrial sterilization coating agents** contained shall be indicated.  
Antifungal agents shall be indicated according to the active ingredient name described in Term 7-(1).

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Tentatively amended: August 22, 2001

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Amended: May 10, 2013

Tentatively amended:

September 18, 2014

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(Antiviral products shall be operated after ISO 21702 is issued)

**Amended: December 14, 2021**

**(The registration of industrial sterilization coating materials shall be operated on or after April 1, 2022)**