# Judging Provisions for Listing of Antifungal Agent in the Positive List

(Note) By establishing these provisions, the "Judging Provisions for Listing of Antifungal Agent in the Positive List K22" shall be deleted and replaced to these provisions.

1. Objective

These provisions stipulate the procedures, judging criteria, etc. to determine whether it is listed or not regarding the application for listing antifungal agents in the Antifungal Agent Positive List of this society.

2. Procedures from the application for listing to the determination whether it is listed or not

(1) Application for listing

The person who applies for listing antifungal agents in the Positive List shall submit the following documents required to judge the listing to the Secretariat of this society.

(i) Application Form (Attached Form 1)
(ii) Antifungal Agent Positive List Entry Sheet (Attached Form 2)
(iii) Copy of the test report showing the safety data

(2) Checking and preparation of application documents

The Secretariat shall examine the submitted documents, confirm whether all the items are filled in and whether it can judge the listing only with the submitted documents, etc., and inform the applicant of the requirement of adding to unfilled items, if any, or of submitting additional documents, if necessary.

If it is too difficult for the Secretariat to judge the appropriateness of documents, the Secretariat may request the Antibacterial Technical Management Committee and the Antifungal Committee to judge by submitting to those committees such documents in which the company name, name of antifungal agent, etc. are deleted to make it impossible to identify the applicant.

According to the opinion and determination of the Secretariat itself, Antibacterial Technical Committee, Management Committee and Antifungal Committee, the Secretariat shall prepare the documents for the Judging Committee required for the judgment of listing by requesting the applicant to correct, add, submit additional documents, etc.

(3) Judgement by the Judging Committee for Listing of the Positive List

The Secretariat shall summon the Judging Committee for Listing and, on the basis of the documents submitted by the applicant, shall request the judgement of the Judging Committee regarding whether it is listed or not in the Antifungal Agent Positive List.

The Judging Committee shall be held with the attendance of members of the Judging Committee, staffs of the Secretariat and the applicant of listing in the Positive List. However, the applicant of listing in the Positive List may only attend the meeting in which the judgment of antifungal agent applied by such applicant is discussed and, if the applicant does not wish to attend, the Judging Committee may be held with the absence of the applicant.

(4) Handling of the judgment result by the Judging Committee

When the Judging Committee has permitted the listing in the Positive List, the Secretariat shall add such antifungal agent to the Antifungal Agent Positive List.

When the Judging Committee has determined that the listing in the Positive List is inappropriate, the Secretariat shall inform the applicant of the judgment result and the reason. When the Judging Committee has requested to correct the documents or submit additional documents and the applicant has submitted such documents to the Secretariat, the judgment shall be discussed again in the Judging Committee which is held thereafter.

3. Judgment criteria

(1) The necessary matter shall be filled in the required items of the Antifungal Agent Positive List Entry Sheet and there shall be no error.

(2) Information on restriction of product use I. Recommended amount to be added II. Maximum blending amount according to each use condition III. Regarding the prohibited use application, the reliability of its fundamental data shall be confirmed from the safety test reports etc. that are the basis for such data, and the logical relation between such data and the information on restriction shall be considered as appropriate.

4. Operation of the Judging Committee for Listing of Antifungal Agent in the Positive List

(1) Members of the Judging Committee

The members are three, consisting of one expert in antifungal agents, one expert in safety and one representative of consumer institutions. The members of the Judging Committee shall be paid remuneration and travelling costs according to the internal rules.

(2) Composition of the Judging Committee

The Judging Committee shall be held with the attendance of members of the Judging Committee, staffs of the Secretariat and the applicant of listing in the Positive List. However, the applicant of listing in the Positive List may only attend the meeting in which the judgment of antifungal agent applied by such applicant is discussed and, if the applicant does not wish to attend, the Judging Committee may be held with the absence of the applicant.

(3) Judgement of listing

The determination whether it is listed or not in the Positive List shall be discussed using the judgement criteria of Term 3, and the listing shall be permitted with a concurring vote of not less than half of the members of the Judging Committee.

(4) The meeting of the Judging Committee shall, as a rule, be held four times a year. However, if there is any specific reason including in the case where the number of application for correction is too large, which can not be processed in four meetings a year, or in the case where there has been no application since the last meeting of the committee, the above-mentioned rule shall not be applied.

5. Confidentiality

(1) The documents submitted by the applicant for the listing of antifungal agent in the Positive List shall be handled in accordance with the Society Document Management Provisions.

(2) The members of the Judging Committee, staffs of the Secretariat, members of the Antibacterial Technical Management Committee and members of the Antifungal Committee must keep the confidentiality of the information contained in the documents submitted by the applicant in the certification review and the information inferable from the same.

Formulated: May 13, 2011
Amended: September 18, 2013
Amended: August 5, 2015

Attachment

Form 1 (Application Form)

Month/Day/Year

To: Society of Industrial Technology for Antimicrobial Articles

Applicant
Address (In the case of corporate body, location of principal place of business )
Name (in the case of corporate body, name of institution or company and name of representative)

In compliance with the "7. Voluntary Specifications for Quality and Safety", I apply the listing of the following antifungal agents in the Positive List.

(The product name of antifungal agent shall be described.)

Form 2 (Antifungal Agent Positive List Entry Sheet)

| | | | |
|---|---|---|---|
| Antifungal agent Product name/Trade name | | | |
| Registration applicant (member) information | | | |
| * | Applicant (company) name | | |
| | Address | | |
| | Name of responsible person | | |
| | Department to which the person belongs | | |
| | Contact address | Address | |
| | | Telephone and Fax | |
| Product content | | | |
| | Chemical name of the effective ingredient of the antifungal agent [1)] | Select and describe the chemical name or the middle classification name in the classification table of antibacterial agents and antifungal agents in the Labeling and Terminology Provisions, or not disclose. | |
| * | Nonproprietary name of the effective ingredient [1)] | - Select and describe the nonproprietary name or the major classification name in the classification table of antibacterial agents and antifungal agents in the Labeling and Terminology Provisions. | |
| | Blending concentration of the effective ingredient [3)] | | |
| | CAS No. [3)] | | |
| | JCSCL No. [3)] | | |
| | Applicable international and national laws<br>① Regulation (substance for which notification is specified or indication is mandatory, etc.)<br>② Registration (domestic and foreign inventory, etc.) | | |
| | Information such as usage results inside and outside Japan | | |

| | | | |
|---|---|---|---|
| Effect of product | | | |
| * | Microbial species | Bacterial strain No. | Test results |
| | *Aspergillus niger* | | |
| | *Penicillium funiculosum* | | |

| | | | |
|---|---|---|---|
| Information on restriction of product use [4)] | | | |
| * | **I** | Recommended amount to be added (highest acceptable compounded amount) | |
| | Supporting data: | | |

| | | | | |
|---|---|---|---|---|
| | **II** | Maximum blending amount according to each use condition | Use condition | Conditional amount to be added (Conditional maximum blending amount) |
| | | | | |
| | | | | |
| | Supporting data: | | | |
| | **III** | Prohibited use application | | |
| | Supporting data: | | | |

Safety/environmental impact information

For the compounding antifungal agent consisting of more than one antifungal ingredient, the safety test must, as a rule, be conducted using compounding ingredient. However, when the blending of each effective ingredient is judged to be less likely to cause chemical change or increasing toxicity, the safety test shall be permitted to be conducted using each effective ingredient. In this case, however, the basis of the determination must be submitted. The method of determination shall be under the chemical structure, biological test and the investigation results with literature etc. concerning cases of human beings.

| | | |
|---|---|---|
| * | Acute oral toxicity | |
| * | Primary skin irritation | |
| * | Mutagenicity 2) | |
| * | Skin sensitization potential | |
| | Higher carcinogenicity test, genetic toxicity | |
| * | Aquatic toxicity | |
| | Octanol/water partition coefficient and solubility to various solvents | |
| | BOD/COD | |
| | other ( ) | |

Items specified by * are the required items and others are optional items.

Note 1) It is desirable that the name of effective ingredient is indicated using either the chemical name or nonproprietary name.

2) When the result of the mutagenicity test is positive, the safety must be verified in its higher carcinogenicity test.

3) Three items in the product content information (blending information of the effective ingredient, CAS-No. and JCSCL number) may be specified as non-disclosure information by the applicant after examination.

4) At least two items of the information on restriction of product use: Information on restriction of use I (maximum blending amount), II (maximum blending amount appropriate to each condition or use), III (prohibited use application) must be indicated. However, item III (prohibited use application) must be inevitably indicated.