

Antimicrobial Science Policies

Disinfectant Technical Science Section (DIS/TSS)

Each of the "DIS/TSS" guidance documents listed below provides a summary of current efficacy-related requirements and/or policy for a category of antimicrobial pesticide products, claims, or patterns of use. If more detailed guidance is needed, the Antimicrobials Division should be consulted ("DIS/TSS" is the acronym for Disinfectant Technical Science Section, the Antimicrobials Division's former Efficacy Evaluation Team).

If any of the product's use patterns is classified as human health related (see DIS/TSS-16), efficacy data must be submitted for review in order to support the inclusion of that use pattern in the product registration. Regardless of the use pattern, however, product efficacy data is required to be maintained in the registrant's files.

The documents may be grouped as follows:

- I. Initial review and label evaluation: DIS/TSS-15, 16
- II. Efficacy data requirements: DIS/TSS-1, 2, 3, 4, 6, 7, 8, 9, 10, 12, 13, 14
- III. Confirmatory efficacy requirements: DIS/TSS-5

The first group helps define the intended pattern of use for a product (for those intended for use on hard surfaces) and helps determine if efficacy testing is required to be submitted. These are in large part dependent on the efficacy claims and directions for use on the product label. It is necessary for these facts to be established before further discussion of efficacy data requirements can be meaningful.

The second group of documents contains efficacy data requirements to support efficacy claims (e.g., levels of antimicrobial activity, types of microorganisms) and specific types of products or patterns of use (e.g., 'one-step' disinfectant/cleaner, food-contact surface sanitizer). Before these requirements can be applied to a product, the intended claims and use patterns must be known (at least in a general way). Standard test methods are intended to support 'standard' claims or use patterns; for other claims and uses, modified methodology may be necessary. Therefore, adequate use directions on the proposed product label are necessary for a specific determination of efficacy testing requirements. In addition, the efficacy testing and reporting must

include all elements necessary for evaluating the methodology employed and the results obtained (see DIS/TSS-2 and -3).

The third group of documents contains confirmatory data requirements. These documents should be used only after the Agency has determined that minimal, confirmatory data is applicable and appropriate for the product in question. Such a determination involves comparison of formulations and manufacturing procedures, adequacy of referenced basic efficacy data, and conformity of claims and directions for use with current labeling requirements. Once 'confirmatory' data is determined appropriate for the product in question, it may be submitted as a supplement to the referenced 'basic' data.

Number	Title	Date
<u>DIS-TSS 01</u>	Disinfectants for Use on Hard Surfaces	Jan. 22, 1982
<u>DIS-TSS 02</u>	Supplemental Recommendations	Jan. 25, 1979
<u>DIS-TSS 03</u>	Reporting of Data	Jan. 29, 1979
<u>DIS-TSS 04</u>	Sanitizing Rinses for Previously Cleaned Food-contacted surfaces	Jan. 30, 1979
<u>DIS-TSS 05</u>	Confirmatory Efficacy Data Requirements	Sept. 22, 1982
<u>DIS-TSS 06</u>	Supplemental Efficacy	
<u>DIS-TSS 07</u>	Virucides (<u>Test Results Table</u>)	Nov. 12, 1981
<u>DIS-TSS 08</u>	Carpet Sanitizers	Apr. 18, 1981

<u>DIS-TSS 09</u>	Sterilizers	
<u>DIS-TSS 10</u>	Sanitizer Test for Inanimate Surfaces	
<u>DIS-TSS 11</u>	Air Sanitizers	Sept. 3, 1980
<u>DIS-TSS 12</u>	Swimming Pool Water Disinfectants	Apr. 23, 1979
<u>DIS-TSS 13</u>	Laundry Additives - Disinfection and Sanitization	Apr. 4, 1980
<u>DIS-TSS 14</u>	Laundry Additives - Residual Self-Sanitization	July 29, 1981
<u>DIS-TSS 15</u>	Label Requirements for Antimicrobial Pesticides Used On Hard Surfaces	Mar. 24, 1981
<u>DIS-TSS 16</u>	Determination of Health- Related and Non-Health-Related Uses	Jun. 26, 1979
<u>DIS-TSS 17</u>	Label Requirements for Pesticides Used for Sanitation of Food Contact Surfaces	Dec. 2, 1979
<u>DIS-TSS 18</u>	Label Requirements for Farm Premise Disinfectants	Jan. 17, 1989
<u>DIS-TSS 19</u>	Label Requirements for Poultry House Disinfectants	Jan. 17, 1980