

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
DIS-TSS 01	Disinfectants for Use on Hard Surfaces	Jan 22, 1982
DIS-TSS 02	Supplemental Recommendations	Jan 25, 1979
DIS-TSS 03	Reporting of Data	Jan 29, 1979
DIS-TSS 04	Sanitizing Rinses for Previously Cleaned Food-contacted surfaces	Jan 30, 1979
DIS-TSS 05	Confirmatory Efficacy Data Requirements	Sep 22, 1982
DIS-TSS 06	Supplemental Efficacy	
DIS-TSS 07	Virucides	Nov 12, 1981
DIS-TSS 08	Carpet Sanitizers	Apr 18, 1981
DIS-TSS 09	Sterilizers	
DIS-TSS 10	Sanitizer Test for Inanimate Surfaces	
DIS-TSS 11	Air Sanitizers	Sep 3, 1980
DIS-TSS 12	Swimming Pool Water Disinfectants	Apr 23, 1979
DIS-TSS 13	Laundry Additives - Disinfection and Sanitization	Apr 4, 1980
DIS-TSS 14	Laundry Additives - Residual Self-Sanitization	Jul 29, 1981
DIS-TSS 15	Label Requirements for Antimicrobial Pesticides Used On Hard Surfaces	Mar 24, 1981
DIS-TSS 16	Determination of Health- Related and Non-Health-Related Uses	Jun. 26, 1979
DIS-TSS 17	Label Requirements for Pesticides Used for Sanitation of Food Contact Surfaces	Dec 2, 1979
DIS-TSS 18	Label Requirements for Farm Premise Disinfectants	Jan 17, 1989
DIS-TSS 19	Label Requirements for Poultry House Disinfectants	Jan 17, 1980