

Consumer Speciality Products Association (CSPA) "Germs" Letter

January 5, 2005

Ms. Brigid D. Klein
Consumer Specialty Products Association
900 17th Street, NW
Washington, DC 20006

Dear Ms. Klein:

CSPA has requested that EPA clarify a March 26, 2004 letter that provides guidance on the use of the term "germs" on antimicrobial labels. Specifically, CSPA requested that the Agency point out in its guidance that the use of the term "germs" on sanitizer products will be addressed at a later time. As a result of making this change, this revised letter will supersede my letter of March 26, 2004.

By way of background, CSPA in a letter dated December 17, 2003 asked the Agency to provide guidance on when the term "germs" can be used on an antimicrobial label. The use of the "germs" term over time has come to be commonly associated with disease causing organisms, including ones caused by bacteria, viruses or fungi. As a result, the Agency considers the term "germs" to be a public health claim which must be supported by appropriate efficacy data. As we have previously discussed, due to the common association of this term with disease bearing organisms, the Agency does not believe that the term can be used as a non-public health claim or on a non-public health product, even if qualified.

The Agency believes the use of the term "germs" must be limited to products which meet certain specified criteria. Further, as previously stated, EPA considers a germ claim to be a broad term that encompasses bacteria, viruses and/or fungi. Those products containing a disinfectant claim including viruses and/or fungi, in addition to a sanitizer claim, may use germ claims. The criteria for obtaining germ claims on disinfecting products is described in more detail below. This guidance is for products that are disinfectants. As previously stated, guidance for sanitizer only products will be addressed at a later time.

Note, in order to use the term “germs” on an antimicrobial label, the product must bear directions for use as a disinfectant. If you remove the disinfectant directions from the label, then you must also remove the term “germs” from the label.

Criteria For A Germs Claim

1. In order to make a qualified “germ” claim on a product label, a product must be registered as a general purpose/broad spectrum disinfectant product with additional label claims against one of the two classes of organisms listed below:

- Fungi - One pathogenic fungi (usually Trichophyton mentagrophytes) that is representative of the use sites listed for the product.
- Viruses - One enveloped and/or non-enveloped virus that is representative of the use sites listed for the product.
- All studies to support disinfectant, fungicidal, and virucidal claims must be conducted according to EPA guidelines.
- The front panel of the label for a qualified public health “germ” claim must contain a designator that refers the user to the qualified statements. A qualified statement is one that clearly describes the type of “germ” the product is efficacious against. When the word “germ” is used on the front panel of a label, an asterisk is required to indicate that there is clarifying language elsewhere on the label.

Examples: Front panel - Kills germs*

Back panel - Kills Salmonella choleraesuis and Staphylococcus aureus

and (list virus or fungi)

2. In order to make an unqualified “germ” claim on a label, a product must have public health data developed using current EPA guidelines for all three of the major classes of organisms:

- Bacteria - meet the general purpose/broad spectrum disinfectant performance standard per EPA guidelines.
- Fungi - One pathogenic fungi (usually Trichopyton mentagrophytes) that is representative of the use sites listed for the product. Studies to be conducted according to EPA guidelines.
- Viruses - One enveloped and non-enveloped virus that is representative of the use sites for the product. Studies to be conducted according to EPA guidelines.
- The claim “germs” can be used without descriptors of the type of organism. No asterisk is required. The claim can appear on the front or back/side panel of a label. However, specific organisms must still be listed on the label.

Examples: Kills Germs
Kills germs in the bathroom and/or kitchen

- Qualified statements are optional and can be added to the product label, if desired.

The Agency intends to implement this guidance immediately. New registration applications will be reviewed using this guidance. The Agency will also apply this guidance when conducting label review of currently registered products. In addition, this guidance will also be used when the Agency conducts label reviews for product specific reregistration.

Sincerely,

Frank T. Sanders, Director
Antimicrobials Division (7510C)