



Regulation of Treated Articles for the U.S. Market

SILVERPLUS[®] products, based on RUCO-BAC AGP POWDER (EPA Reg. No. 49403-34-084189), later on called "SILVERPLUS[®]" are antimicrobial additives to be used to treat textiles. They are designed to be incorporated during the finishing process to impart antimicrobial activity of the finished textile products. SILVERPLUS[®] suppresses the growth of bacteria which cause unpleasant odors, discoloration, staining or deterioration. No finished product incorporating SILVERPLUS[®] may make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the finished product which permits such claims. The U.S. Environmental Protection Agency (EPA) regulatory requirements associated with treated fabrics and surfaces are complex. Specific label claims made on finished textiles treated with SILVERPLUS[®] may trigger EPA regulatory jurisdiction and the requirement to register the finished product with the EPA. Products that incorporate SILVERPLUS[®] are subject to the labeling requirements as identified in the U.S. "Treated Article Exemption Policy" (PR Notice 2000-1, http://www.epa.gov/PR_Notices/pr2000-1.pdf)

Any product offered for sale in the U.S. that claims to control or mitigate pests, including microorganisms, must be registered by the EPA. However, the EPA will exempt, from the registration requirements, articles that have been treated with an antimicrobial preservative such as SILVERPLUS[®] provided the label claims on the finished article are limited to preservation of the article itself and not protection of the user against pathogenic organisms.

EPA will allow what they consider "non-public health" claims as identified in PR Notice 2000-1 on products. Examples of acceptable non-public health claims would include:

- claims to inhibit or prevent the growth of odor causing bacteria;
- claims to inhibit the growth of mildew or mold that may cause deterioration of the product.

Examples of unacceptable claims include:

- antibacterial, bactericidal, germicidal;
- controls both gram positive and negative bacteria.

To ensure compliance with U.S. EPA regulations, you may wish to hire an expert in the area of the U.S. treated article policy. Rudolf GmbH recommends Technology Sciences Group Inc. located in Washington, DC. (www.tsgusa.com). For further information, please contact, Erin Tesch at etesch@tsgusa.com or 202-828-8966.