

TECHNICAL BULLETIN

Requirements for Surface Sanitizers to be FDA Food Code Compliant

- 1. Federal and State Registration:** The product must be registered with the **EPA** and have an EPA registration number. The product must also be registered in the state that it is being used in.
 - a. FDA does not review and approve food contact surface sanitizers.
 - b. Jurisdiction for antimicrobial substances used to sanitize or disinfect food-contact surfaces was transferred to the EPA under the Food Quality Protection Act (FQPA) passed by Congress in 1996 (<http://npic.orst.edu/reg/laws.html>).
 - c. EPA must review the product formulation, acute toxicity, and efficacy data as well as approve/prescribe product labeling
 - i. In order for EPA to permit labeling for Food Contact Surface Sanitizing with no rinse required EPA must check that the active ingredient and any inert ingredients are acceptable for this use per 7-204.11 Sanitizers, Criteria of the 2013 Food Code (referencing 40 CFR 180.940, 950, or 960). The 2005 - 2013 FDA Food Code recognizes this.
 - ii. EPA must review the efficacy data and assure that the product kills 99.999% of bacteria within 30 seconds (*Staphylococcus aureus* and *E. Coli*). Note: Even though a product has proven to kill 99.999% of bacteria in 30 seconds or less and FDA Food Code requires a contact time of at least 30 seconds for other chemical sanitizing solutions, EPA requires that a product's directions for use indicate 60 seconds for sanitizing food contact surfaces.
- 2. Test Device:** A test kit or other device that accurately measures the active concentration level of sanitizing solutions must be available as per 4-302.14 Sanitizers, Criteria of the 2013 Food Code.
- 3. Follow Directions for Use:** If a sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions.
 - a. As identified above within Federal Registration, EPA will approve as well as prescribe product labeling.
 - b. An area that is prescriptive is the 'directions for use' for EPA registered food contact surface sanitizers. EPA requires food contact surface sanitizers to indicate a 60-second dwell time even if the product has data that proves 99.999% reduction of bacteria in 30 seconds or less.

PURELL® Foodservice Surface Sanitizer Complies with **FDA FOOD CODE**

1. Federal and State Registration:

- a. PURELL Foodservice Surface Sanitizer is an EPA registered surface sanitizer/disinfectant (EPA Reg. No. 84368-1-84150) approved for use on food-contact surfaces with no rinse required and is currently registered in all 50 states.
- b. All ingredients in PURELL Foodservice Surface Sanitizer have been reviewed by EPA and found to meet requirements for use on food contact surfaces and not requiring a rinse.
 - i. NOTE: Food Code does not prohibit the use of ethanol as active ingredient. The Food Code requires that the registration holder demonstrate to the regulatory authority (EPA) that the solution achieves sanitization.
- c. PURELL Foodservice Surface Sanitizer is approved by EPA with the level of ethanol active ingredient in the range of 28.5 to 30.3%, however there is no upper limit for amount of ethanol that can be used on a food contact surface per 40 CFR 180.940.
- d. Product quality is verified before shipping to ensure the level of ethanol active ingredient and since the product is ready to use there is no risk of mixing incorrectly.

2. Test Device: to support the use of this product, specifically in back-of-house on food contact surfaces, test strips to measure active ingredient concentration are available to the end user as specified by the 2013 FDA Food Code.

3. Follow Directions for Use: The PURELL Foodservice Surface Sanitizer product is acceptable for use in foodservice establishments as long as it is used in accordance with the EPA-registered label use instructions.

ANSWERS TO COMMON QUESTIONS:

• WHAT ARE THE APPROVED USES FOR THE PRODUCT?

- PURELL Foodservice Surface Sanitizer is EPA-approved for surface sanitizing and cleaning in both Front of House and Back of House. It is approved for use on both non-food contact surfaces and food contact surfaces with no rinse required.
- Facilities should always follow Food Code guidance for cleaning and sanitizing food contact surfaces. In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the requirements in Parts 4-6 and 4-7 of the Food Code, the surface must be first cleaned properly to remove organic material.
 - **For Food Contact Surfaces**, PURELL Foodservice Surface Sanitizer may be used for both the pre-clean steps as well as the sanitization steps and no rinse is required. For example:
 1. Scrape: Scrape excess/visible food away from surface.
 2. Wash: Spray PURELL Foodservice Surface Sanitizer on surface; then, wipe with a clean towel. No rinse is required.
 3. Sanitize: Spray PURELL Foodservice Surface Sanitizer on surface again and allow to air dry.
 - **For Non Food Contact Surfaces**, PURELL Foodservice Surface Sanitizer may be used to sanitize and clean in one-step. For example:
 1. Sanitize: Spray PURELL Foodservice Surface Sanitizer on surface and allow to remain wet for 60 seconds. Wipe or allow to air dry.

• WHAT ARE THE ACCEPTABLE LOW AND HIGH LEVELS OF THE PRODUCT?

- PURELL Foodservice Surface Sanitizer is approved by EPA with the level of ethanol active ingredient in the range of 28.5 to 30.3%, however there is no limit for amount of ethanol that can be used on a food contact surface per 40 CFR 180.940.
- Test strips accurately measure ethanol levels and ensure levels meet EPA approved specifications.

• WHERE SHOULD YOU STORE THE PURELL FOODSERVICE SURFACE SANITIZER AND ASSOCIATED TEST KIT?

- Always store PURELL Foodservice Surface Sanitizer and Test Kit materials in a designated chemical closet.