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Manufacturer's Guidance for PURELL® Hand Sanitizer Products

It is unsafe and does not meet regulations when PURELL Hand Sanitizer packages (dispensing systems and pump bottles) are used to dispense products other than PURELL Hand Sanitizer. In the U.S, hand sanitizers are FDA-regulated OTC drug products that are produced and marketed as required under FDA Topical Antimicrobial Drug Products Monograph.

GOJO Industries develops, tests, manufactures and markets its PURELL Hand Sanitizer products in strict accordance with FDA requirements. PURELL Hand Sanitizer packages present key product information such as lot codes, expiration dates, and drug facts that are required by the FDA.

- Using PURELL branded packaging to dispense other products:
  - Is misleading
  - Is a violation trademark law *
  - Is a violation of the Federal Food, Drug, and Cosmetic Act **
  - Is a violation of Federal Food, Drug, and Cosmetic Act CGMP regulations ***

- Refilling PURELL Hand Sanitizer with other products could result in chemistry that:
  - Is not effective in killing germs
  - Could cause bodily harm or injury

* See Lanham Act at 15 USC sections 1051 *et seq*.

** Under the Federal Food, Drug, and Cosmetic Act, a drug product label that contains false or misleading information causes the drug product to be misbranded. Using PURELL containers and dispensers that contain non-PURELL product causes them to be misbranded because the product labeling is no longer truthful and is misleading, including with regard to the ingredients, expiration date, and origin of the product.

*** The failure comply with Currently Good Manufacturing Practice (CGMP) requirements renders drug products adulterated as a matter of law.