



April 2, 2018

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To whom it may concern:

Thank you for your inquiry regarding GOJO Industries' PURELL® and PROVON® Antimicrobial Foam Handwash with 2% CHG. CHG handwashes have been used in healthcare institutions for over 30 years, and PURELL and PROVON Antimicrobial Foam Handwash with 2% CHG have been reviewed by the FDA, and determined to be both safe and effective for use as a healthcare personnel hand wash or surgical scrub.

PURELL and PROVON Antimicrobial Foam Handwash with 2% CHG contain cocamide diethanolamine (CDEA). CDEA is a fragrance solubilizer, a foam booster, and a viscosity modifier. CDEA is an ingredient in all 2% CHG handwash products currently available for the healthcare market and is the basis for the classification of H351 - *Suspected of causing cancer*. This classification is based on tumors observed in a study in mice. In that study, a solution containing 99% pure CDEA was dissolved in alcohol and applied to the skin of mice five days per week for two years. During the study, the applied product was never washed off. Notably, rats treated in a similar manner did not develop tumors.

A third-party consulting toxicologist, in conjunction with GOJO, conducted an evaluation of the amount of CDEA in PURELL and PROVON Antimicrobial Foam Handwash with 2% CHG. A comparison of the exposure values obtained in that evaluation to regulatory exposure benchmarks showed that the estimated exposure of healthcare workers to CDEA is less than the reference regulatory benchmarks. Because a number of conservative assumptions were used to estimate exposures of healthcare workers, there is a high level of confidence that actual exposure to CDEA under typically anticipated use conditions for the product will be substantially less than calculated. In conclusion, exposure to CDEA in the product is too low to be of concern and the product is safe for use as recommended.

Despite the safety evaluation of the product, we are obligated, under the new GHS hazard classification scheme, to classify products strictly according to the presence of chemicals in the formulation, regardless of how low the level of exposure is to the ingredient.

If I can provide any additional information, please feel free to contact me directly.

Regards,

A handwritten signature in black ink, appearing to read "Antonio Quinones-Rivera". The signature is fluid and cursive, written over the printed name.

Antonio Quinones-Rivera, Ph.D.  
Product Safety and Sustainability Manager  
GOJO Industries