

Monitoring SARS-CoV-2 Developments

Federal Drug Administration Hand Sanitizer Advisory

July 14, 2020

As states proceed through reopening and workers return to office, retail and manufacturing facilities, we at RHP Risk Management assist clients in monitoring the ongoing and fast paced development of SARS-CoV-2 information. In earlier circulations, RHP's Jason Lang, CIH and Frank Pagone, PhD provided insights and guides to a return to work, [Preparing Workplaces for Re-entry](#) and [Pandemic Infectious Disease Plan: Returning to a New Normal](#).



Recently, the U.S. Food and Drug Administration (FDA) provided alerts concerning the use of certain hand sanitizers that contain methanol, highlighting the need for employers to keep abreast of developing knowledge and to follow best practices when adding new chemical products to the workplace.

As sanitization stations are a recommended part of return to work infectious disease plans, their regular use and the current product availability may make it challenging to keep these stations stocked and ready. To help meet this demand, the FDA relaxed rules on the manufacture of hand sanitizer. Entities that are not currently FDA registered drug manufacturers are able to register as over-the-counter (OTC) drug manufacturers to manufacture and distribute alcohol-based hand sanitizers; pharmacies and registered outsourcing facilities are able to compound alcohol-based hand sanitizers; and alcohol production firms may produce alcohol for making hand sanitizers provided they follow the conditions outlined in the FDA guidance for industry. Since March, an additional 1,500 manufacturers have entered the hand sanitizer market as a response to SARS-CoV-2. While the FDA has recommended that manufacturers denature alcohol and limit harmful impurities, these recommendations are nonbinding. With the number of new manufacturers and hand sanitizing products entering the market, the regulators are finding it impossible for testing to have been conducted on all products.

On June 19, 2020, the [FDA issued a "do not use" warning](#) nine hand sanitizer products manufactured by Eskbiochem SA de CV in Mexico, on the basis of samples tested showing as much as 81% methanol / wood alcohol. Methanol can result in toxicity through dermal contact, ingestion, or inhalation of fumes. Symptoms of substantial exposure to methanol may include nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system, or death. The brand names in the initial FDA warning included All-Clean Sanitizer; EskBiochem Hand Sanitizer; CleanCare NoGerm Advanced Hand Sanitizer 75% Alcohol; Lavar 70 Gel Hand Sanitizer; the Good Gel Antibacterial Gel Hand Sanitizer; CleanCare NoGerm Advanced Hand Sanitizer 75% Alcohol; two lots of CleanCare NoGerm Advanced Hand Sanitizer 80% Alcohol; and Saniderm Advanced Hand Sanitizer. While the FDA contacted the manufacturer, Eskbiochem, on June 16 to recommend the removal of the hand sanitizer products and alerted consumers, it was not until June 29, 2020 that the FDA updated their alert to state that Saniderm Products and UVT Inc. had initiated a voluntary recall of all Saniderm Advanced

Hand Sanitizer products produced by Eskbiochem SA de CV with a “Made in Mexico” origin. On July 1, the FDA recommended a recall on further products originating in Mexico that were tested and found to contain methanol. The products and manufacturers vary and include Hand Sanitizer Gel Unscented 70% Alcohol (Grupo Insoma, S.A.P.I de CV); Mystic Shield Protection hand sanitizer (Transliquid Technologies); Berish Hand Sanitizer Gel Fragrance Free (Soluciones Cosméticas SA de CV); Antiseptic Alcohol 70% Topical Solution Hand Sanitizer (Soluciones Cosméticas SA de CV); and Britz Hand Sanitizer Ethyl Alcohol 70% (Tropiscosméticos SA de CV). The FDA maintains a table warning of products tested and found to contain methanol, many purportedly manufactured at the same facility or distributed by the same distributor as products already tested and cautioned against use by the FDA. The FDA list continues to be updated, and as of July 13, 2020 there are 59 hand sanitizer products that are no longer recommended. (<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol>)

Of the products the FDA has identified as do not use, they advise disposing of any full or remaining containers of the hand sanitizer immediately in appropriate hazardous waste containers. Those who have been exposed to these hand sanitizers containing methanol should seek immediate treatment for potential reversal of toxic effects of methanol poisoning. If a person experiences a serious reaction to hand sanitizer, the FDA further recommends reporting the adverse reactions to their [MedWatch Adverse Reporting Program](#).

Steps to choosing safe products such as hand sanitizer include the use of recognized and recommended brands, reading and understanding product labels and ingredients, and requesting Safety Data Sheets (SDS). Always when adding new chemical products to any workplace, it is recommended that employers keep records of and/or post SDSs for the new products, as well as add any other safety measures, such as wash stations and eye wash stations, based on all products used in your workplace. Since information and guidance surrounding the COVID-19 pandemic are evolving, it is important to follow recognized and reliable sources such as the FDA and CDC. RHP Risk Management’s experienced and trained public health and scientific professionals continue to monitor, audit and assess the evolving information on the SARS-CoV-2 pandemic and to develop programs, systems and plans for clients to maintain a healthy and safe workplace and facility.

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