

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

February 11, 2022

OFFICE OF LAND AND EMERGENCY MANAGEMENT

Ms. Jennifer Gibson Vice President, Regulatory Affairs National Association of Chemical Distributors 4201 Wilson Blvd. Suite 0515 Arlington, Virginia 22203

Dear Ms. Gibson:

I am writing to follow up on your letter from January 4, 2022, and our call on Monday, January 31, 2022. In the letter and meeting you informed EPA that on October 12, 2021, FDA announced that it is withdrawing its temporary guidance for alcohol-based hand sanitizers. As a result, effective Dec. 31, 2021, companies manufacturing alcohol-based hand sanitizers under the FDA's temporary policies had to cease production of these products. Further, hand sanitizers manufactured before or on December 31, 2021, and produced under the temporary guidances can no longer be sold or distributed by manufacturers after March 31, 2022. You expressed concern that your members do not have sufficient time to sell or donate their stock in that timeframe and they will be forced to discard the leftover hand sanitizer. Because alcohol-based hand sanitizers are ignitable hazardous waste (D001) under RCRA, you expressed concern that this could be a financial burden on your members that manufactured hand sanitizer under FDA's temporary guidance. You asked whether EPA regulations might allow repurposing or recycling of the hand sanitizer.

Based on our discussions with you, our understanding is that while some of the hand sanitizer is in bulk form, much of it is already packaged for retail sale. While the applicable RCRA regulations would be the same regardless of whether it is bulk or packaged for retail use, as a practical matter, the consumer packaging may inhibit the recyclability of the hand sanitizer. That is, the leftover bulk product may have some potential for recycling; unfortunately, the opportunities for recycling are likely reduced when the hand sanitizer is in consumer packaging. We will discuss the hand sanitizer that is in consumer packaging separately from the bulk hand sanitizer.

One of RCRA's goals is to minimize waste generation when possible. Given that it will be difficult to recycle the hand sanitizers that are packaged for retail, EPA first and foremost would like to work with NACD and FDA to evaluate any options that would avoid discarding what is otherwise a useful product. EPA recognizes and commends the NACD members who stepped up to manufacture and distribute needed hand sanitizer during the early days of the COVID-19 pandemic. We have reached out to FDA to engage them on this issue.

If these attempts to find another solution do not prove fruitful and the packaged hand sanitizer must be disposed as hazardous waste, your member companies may want to explore the possibility of disposing of the excess hand sanitizer under the episodic generator provisions of 40 CFR 262, Subpart L. These provisions allow a very small quantity generator or small quantity generator to maintain their generator category while generating an increased amount of hazardous waste that does not normally occur during their operations, as long as certain conditions are met. For example, the generator would need to notify using the Site ID form, 8700-12, and send the episodic hazardous waste to a designated facility within 60 days, among other conditions. Please have your members check with their authorized state to determine if the episodic generation provisions are available.

With respect to the bulk hand sanitizer, under the RCRA regulations, an item must first be a solid waste before it can be a hazardous waste. In this case, the hand sanitizer would be considered a commercial chemical product. A commercial chemical product is not a solid waste when it is reclaimed. For example, if a hand sanitizer manufacturer (or a third party) could extract ethanol from the hand sanitizer and the ethanol could be used as in ingredient to make a new product, then the hand sanitizer would not be a solid waste. As with all recycling, it must be done in compliance with the legitimate recycling regulations in 40 CFR 260.43.

Hand sanitizer that is not a solid waste because it is destined for legitimate recycling may be stored as a commercial chemical product without needing a RCRA storage permit or otherwise being subject to RCRA hazardous waste requirements. Companies that store such hand sanitizers prior to recycling must be prepared to demonstrate that there is a known market or disposition for the material, and be able to provide appropriate documentation (such as contracts showing that a second person uses the material as an ingredient in a production process) to demonstrate that the material is not a waste, per 40 CFR 261.2(f).

We hope you and your members find this information about the RCRA recycling regulations useful. As I said above, we have reached out to FDA to engage them on this issue. In the meantime, if you have any further questions, please contact Kristin Fitzgerald at fitzgerald.kristin@epa.gov or (202) 566-0512.

Sincerely,

Carolyn Hoskinson, Director
Office of Resource Conservation and Recovery

¹ A commercial chemical product listed in 40 CFR 261.33 that is reclaimed is not a solid waste (see <u>40 CFR 261.2(c)(3)</u> and Table 1 in 261.2). Previous EPA guidance has clarified that a commercial chemical product that is a characteristic hazardous waste is also not a solid waste when reclaimed (see memo dated July 11, 1994; <u>RCRA Online #11848</u>).