

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

November 17, 2022

OFFICE OF LAND AND EMERGENCY MANAGEMENT

<u>MEMORANDUM</u>

SUBJECT: RCRA Management of Excess Alcohol-based Hand Sanitizer

FROM: Carolyn Hoskinson, Director

Office of Resource Conservation and Recovery

TO: Regional RCRA Division Directors

During the COVID-19 pandemic, the demand for hand sanitizer surged. Many companies stepped up to respond to the demand. Some of those companies were traditional hand sanitizer manufacturers, others were not but adapted their processes to meet the Food and Drug Administration's (FDA) temporary guidance for alcohol-based hand sanitizers. Now many businesses, schools and other organizations that manufactured or acquired large amounts of hand sanitizer during the COVID-19 pandemic are finding that the sanitizer is reaching expiration dates. Additionally, on October 12, 2021, FDA announced the withdrawal of its temporary guidance for alcohol-based hand sanitizers. As a result, effective December 31, 2021, companies that manufactured 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 guidance could no longer be sold or distributed by manufacturers after March 31, 2022.

EPA has issued two previous memoranda about hand sanitizer that are still relevant:

- 1. From Hoskinson to Gibson; February 11, 2022; RCRA Online #14941
- 2. From Kirkland to Harriz; January 24, 2021; RCRA Online # 14949

Because many entities now have excess hand sanitizer in their possession, the Office of Resource Conservation and Recovery (ORCR) and EPA regional offices continue to receive requests for clarification of the regulatory status of discarded or reclaimed alcohol-based hand sanitizer, particularly about ethanol-based hand sanitizer. In addition, EPA has received recent reports of mismanagement of excess hand sanitizer, including warehouses of stockpiled hand sanitizer that have experienced significant fires. This has prompted the need for further EPA guidance beyond the two existing memoranda.

The purpose of this memo is to provide additional details about how RCRA hazardous waste regulations and exemptions apply to different scenarios for recycling excess alcohol-based sanitizer. After providing some background, we address the regulatory status of five recycling scenarios, followed by a discussion of the safety considerations and RCRA regulations that apply to generators managing hand sanitizer. While EPA encourages recycling of excess hand sanitizer whenever

 $^{^{1}\,\}underline{\text{https://www.fda.gov/news-events/press-announcements/fda-brief-fda-withdrawing-temporary-guidances-alcohol-based-hand-sanitizers}.$

possible, we stress the need to make sure all excess hand sanitizer is managed safely, and that recycling is done in compliance with the legitimate recycling regulations in 40 CFR 260.43.

This table provides a summary of four of the five recycling scenarios that are detailed in Section II.

If the hand sanitizer is		Then
1. Burned for energy recovery		The hand sanitizer is a solid and hazardous waste subject to RCRA Subtitle C regulation (Part 266 Subpart H)
2. Used in a manner constituting disposal (e.g., in a product that is used in or on the land)		The hand sanitizer is a solid and hazardous waste subject to RCRA Subtitle C regulation (Part 266 Subpart C)
3. Reclaimed to produce alcohol, and	The alcohol is burned for energy recovery	The hand sanitizer and reclaimed alcohol are solid and hazardous waste subject to RCRA Subtitle C regulation (Part 266 Subpart H)
	The alcohol is used in a manner constituting disposal	The hand sanitizer and reclaimed alcohol are solid and hazardous waste subject to RCRA Subtitle C regulation (Part 266 Subpart C)
4. Reclaimed to produce alcohol, and	The alcohol is used in a product that is <u>not</u> burned for energy recovery and <u>not</u> used in a manner constituting disposal	The hand sanitizer and reclaimed alcohol are not a solid and hazardous waste and are exempt from RCRA Subtitle C regulation, provided the recycling is legitimate per 40 CFR 260.43

I. Background

Excess Alcohol-based Hand Sanitizer Can Be Considered a Solid and Hazardous Waste

According to the FDA, only ethanol (also known as ethyl alcohol) and isopropyl alcohol (also known as 2-propanol) are acceptable alcohols in hand sanitizer.² Alcohol-based hand sanitizer typically contains at least 60 percent alcohol by volume; therefore, it is an ignitable hazardous waste when discarded (D001). Other types of alcohol, including methanol and 1-propanol, are not acceptable in hand sanitizer because they can be toxic to humans.³ Nevertheless, off-spec hand sanitizers that contain methanol and 1-propanol would also be ignitable hazardous waste when discarded.

Excess hand sanitizer can become a waste when it cannot be used or reused for its intended purpose. As discussed below, under some circumstances, hand sanitizer can be a solid waste and hazardous waste even when it is recycled. Although most of the regulations that apply to determining whether a hazardous secondary material is a solid waste are in 40 CFR 261.2(c), the parenthetical in 40 CFR 261.3(c)(2)(i) is also relevant:

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² https://www.fda.gov/consumers/consumer-updates/your-hand-sanitizer-fdas-list-products-you-should-not-use.

³ Ibid

However, materials that are reclaimed from solid wastes and that are used beneficially are not solid wastes and hence are not hazardous wastes under this provision unless the reclaimed material is burned for energy recovery or used in a manner constituting disposal.

Note that while 40 CFR 261.2(c)(2)(ii) states that commercial chemical products are not solid waste when burned for energy recovery when "they are themselves fuels," 40 CFR 261.3(c)(2)(i) does not contain a similar exception.

II. Regulatory Status of Five Recycling Scenarios

1. Hand Sanitizer that is Burned for Energy Recovery is a Solid and Hazardous Waste

Excess alcohol-based hand sanitizer is a commercial chemical product under 40 CFR 261.2. When a commercial chemical product is burned for energy recovery it is considered a solid waste unless the commercial chemical product is itself a fuel. Excess hand sanitizer is a solid and hazardous waste when burned for energy recovery because hand sanitizer is not a fuel (40 CFR 261.2(c)(2)).⁴

Hand sanitizer may be burned for energy recovery, but it is regulated as a hazardous waste throughout its management, starting from its generation and continuing through transport and delivery to and management at the destination facility. Further, the unit burning the hand sanitizer would likely be regulated as a boiler or industrial furnace under 40 CFR part 266 subpart H (Hazardous Waste Burned in Boilers and Industrial Furnaces) and thus would need a RCRA permit.

2. Hand Sanitizer that is Used in a Manner Constituting Disposal is a Solid and Hazardous Waste

When a commercial chemical product is applied to or placed on the land, or used to produce products that are applied to or placed on the land, it is considered a solid waste, unless that is its ordinary manner of use (40 CFR 261.2(c)(1)). Excess hand sanitizer is a solid and hazardous waste when placed on the land because that is not its ordinary manner of use. As a result, the regulations in 40 CFR part 266 subpart C (Recyclable Materials Used in a Manner Constituting Disposal) would apply to hand sanitizer that is placed on the land or that is contained in products or mixtures that are placed on the land. Among other things, part 266 subpart C requires compliance with the regulations for hazardous waste generators; transporters; treatment, storage and disposal facilities; as well as the treatment standards in the land disposal restrictions.

3. When Alcohol is Reclaimed from Hand Sanitizer and the Reclaimed Alcohol is Burned for Energy Recovery or Used in a Manner Constituting Disposal, the Hand Sanitizer and Reclaimed Alcohol are Solid and Hazardous Wastes

In our 2021 letter to USDA, 6 we stated:

Hand sanitizer going to reclamation would not be regulated as a hazardous waste unless the reclaimed alcohol is burned for energy recovery or used to make a fuel.

⁴ Previous EPA guidance has clarified that this applies to commercial chemical products regardless of whether they are listed hazardous waste or exhibit a characteristic of hazardous waste. From Bussard to Gable, July 11, 1994, <u>RCRA Online #11848</u>.
⁵ Ibid

⁶ From Kirkland to Harriz, January 24, 2021; RCRA Online # 14949.

We have received numerous questions about this statement since the letter to USDA was published. Today, we are reiterating this statement and providing additional explanation.

As EPA stated in a 2018 memorandum:⁷

EPA statements about burning for energy recovery (and the other forms of recycling that involve discard) have been consistent since the earliest hazardous waste findings and regulations. Preamble statements have consistently noted that solid waste exclusions and exemptions do not apply to recycling of "inherently waste-like" materials, recycling of hazardous secondary materials that are "used in a manner constituting disposal," or "burning of hazardous secondary materials for energy recovery."

As an example of prior statements, a 1998 memorandum stated (emphasis added in italics):⁹

Although the federal regulations provide, generally, that characteristic by-products and sludges that are reclaimed are not solid waste [40 CFR 261.2(c)(3)], the regulations expressly override that determination when these materials are 1) used in a manner constituting disposal; 2) used to produce products that are applied to the land; 3) burned for energy recovery, used to produce a fuel, or contained in a fuel; 4) accumulated speculatively; or 5) considered inherently wastelike (40 CFR 261.2(e)(2)). Accordingly, metal-bearing characteristic byproducts and sludges that are reclaimed are solid wastes subject to the applicable Subtitle C regulatory requirements when the waste or reclaimed materials are then used or reused in a product (such as fertilizer) that is to be placed on the land (i.e., used in a manner constituting disposal).

Additionally, a 1999 memorandum emphasizes that the entire recycling chain of events must be considered (emphasis added in italics):¹⁰

For instance, characteristic sludges that are reclaimed are generally not considered solid wastes (Section 261.2(c)(3)). However, a facility that first reclaims a characteristic sludge and then places it on the land *must consider the entire recycling process*, *not just the first step in the process*, and must classify the sludge as a solid waste, because the product was ultimately recycled in a manner constituting disposal (Section 261.2(c)(1)).

To reiterate, when materials are reclaimed from characteristic by-products and characteristic sludges and then burned for energy recovery or used in a manner constituting disposal, both the original material (i.e., characteristic by-product or characteristic sludge) and the reclaimed material are solid and hazardous waste. The same reasoning holds true for listed or characteristic commercial chemical products. That is, the entire chain of events must be considered when determining whether a commercial chemical product that is destined for reclamation is a solid and hazardous waste. Put another way, the intended use of the reclaimed material must be considered when determining whether a commercial chemical product that is destined for reclamation is a solid and hazardous waste.

⁷ From Johnson to Kin, January 26, 2018, RCRA Online #14900.

⁸ In promulgating its first RCRA hazardous waste regulations, EPA incorporated fundamental principles about the need to regulate certain materials and processes even when they involve recycling. 50 FR 614, 637 (Jan. 4, 1985).

⁹ From Bussard to Reilly, February 13, 1998, RCRA Online #14195.

¹⁰ June 1999 Q&A; RCRA Online #14348.

Finally, the U.S. Court of Appeals for the District of Columbia Circuit has ruled that the language of RCRA § 3004(q) makes Congress's directive to regulate hazardous-waste-derived fuels mandatory, and that this mandate is broadly inclusive. ¹¹ In accordance with this decision, EPA considers alcohol derived from the reclamation of hand sanitizer to be a hazardous-waste-derived fuel.

4. When Alcohol is Reclaimed from Hand Sanitizer and the Reclaimed Alcohol is not Burned for Energy Recovery or Used in a Manner Constituting Disposal, the Hand Sanitizer and Reclaimed Alcohol are not Solid or Hazardous Wastes

Per 40 CFR 261.2(c)(3), excess alcohol-based hand sanitizer is a commercial chemical product and is not a solid waste when it is reclaimed, provided the reclaimed product is not used as a fuel or burned for energy recovery, or used in a manner constituting disposal. For example, if a hand sanitizer manufacturer (or a third party) extracts alcohol from the hand sanitizer, and the alcohol is used as in ingredient to make a new non-fuel product, then neither the hand sanitizer nor the reclaimed alcohol would be a solid waste. As with all recycling, it must be done in compliance with the legitimate recycling regulations in 40 CFR 260.43.

5. Exemption for Industrial Ethyl Alcohol that is Reclaimed Does Not Apply to Unused Alcoholbased Hand Sanitizer

Industrial ethyl alcohol that is reclaimed is not regulated as a hazardous waste per 40 CFR 261.6(a)(3)(i). When EPA promulgated this exemption in 1985, we provided this rationale: 14

Industrial ethyl alcohol can become contaminated during use, and may then be returned to a distillery for redistillation...EPA has decided to exempt industrial ethyl alcohol that is reclaimed from any RCRA regulations because the entire reclamation process is already regulated by the Bureau of Alcohol, Tobacco and Firearms from the point of spent ethyl alcohol generation to point of redistillation. These regulations require operating permits for individual industrial ethyl alcohol distilleries and users. These permits must address (among other things) ethyl alcohol storage (including storage of spent ethyl alcohol), plant security, and recordkeeping.

The preamble makes it clear that this exemption was created to address spent industrial ethyl alcohol that would otherwise be a solid and hazardous waste when reclaimed (see Table 1 in 40 CFR 261.2(c)). Excess alcohol-based hand sanitizer is a commercial chemical product, not a spent material, and therefore this exemption is not relevant or necessary; instead, the exemption in 40 CFR 261.2 for reclaiming commercial chemical products should be applied.

The Alcohol and Tobacco Tax and Trade Bureau¹⁵ (TTB) regulates the manufacture as well as certain uses of industrial ethyl alcohol under Title 27 of the Code of Federal Regulations. Alcohol-based

¹¹ NRDC v. EPA, 755 F.3d 1010 (D.C. Cir. 2014) (overturning the exclusion from RCRA regulation for "comparable fuels").

¹² From Straus to Walka, April 28, 1986, RCRA Online #11147.

¹³ From Williams to Gray, January 29, 1988, RCRA Online #11321.

¹⁴ 50 FR 649; January 4, 1985.

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¹⁵ In 2003, the Bureau of Alcohol, Tobacco and Firearms was split and renamed. The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) is a law enforcement agency within the Department of Justice. The Alcohol and Tobacco Tax and Trade Bureau (TTB) is within the Department of Treasury.

hand sanitizer would be classified as an "industrial" use of "distilled spirits" (i.e., ethyl alcohol) under the criteria set forth in TTB's regulations at 27 CFR 1.60 and 1.62. Nevertheless, even though alcohol-based hand sanitizer would be considered industrial ethyl alcohol, as explained above, since the excess hand sanitizer is not spent, the exemption in 261.6(a)(3)(i) would not be applicable. In the case when an industrial ethyl alcohol is spent and is being reclaimed, it is not regulated under the RCRA hazardous waste regulations, provided all applicable TTB regulations are complied with.

III. Safety Considerations and RCRA Regulations when Managing Ignitable and Flammable Hand Sanitizer

Safety Considerations

Regardless of whether hand sanitizer is a solid or hazardous waste under RCRA, we stress the need to manage it safely and in compliance with all federal, state, and local requirements. We bring your attention to two areas of regulation, in particular:

- Storage. The National Fire Protection Association (NFPA) has developed dozens of codes and standards related to fire hazards. NFPA 30 is entitled Flammable and Combustible Liquids Code and applies to the storage of hand sanitizer, whether it is a product or a waste. Enforceable under the Occupational Health and Safety Administration (OSHA) regulations, as well as many state and local regulations, NFPA 30 provides safeguards to reduce the hazards associated with the storage, handling, and use of flammable and combustible liquids. 16
- 2. <u>Transportation</u>. While a commercial chemical product being reclaimed does not need to be manifested as a hazardous waste when being returned to the manufacturer (or third party) for reclamation, if the commercial chemical product is a hazardous material as defined by the Department of Transportation (DOT), it would still need to follow all applicable DOT regulations.

RCRA Requirements for Non-Waste Hand Sanitizer

Excess alcohol-based hand sanitizer that is not a solid waste because it is destined for legitimate reclamation may be stored as a commercial chemical product without needing a RCRA storage permit or otherwise being subject to RCRA hazardous waste requirements. The hand sanitizer must be managed as a valuable commodity per 40 CFR 260.43(a)(3) as well as meet the other legitimacy factors described in 40 CFR 260.43. As part of being managed as a valuable commodity, the hand sanitizer would need to either be managed consistent with the analogous raw material or meet the "contained" standard in 40 CFR 260.10, which includes addressing "any potential risks of fires or explosions."

Anyone that stores 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). It should be noted that entities could be cited for illegally storing hazardous waste if they cannot prove that their hand sanitizer meets a solid waste exclusion under RCRA.

¹⁶ https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=30.

RCRA Requirements for Generators of Hand Sanitizer that is a Solid and Hazardous Waste

Managing excess alcohol-based hand sanitizers that are solid and hazardous waste requires full cradle-to-grave management under RCRA, including (but not limited to) hazardous waste notification, hazardous waste labeling and accumulation standards, manifesting, hazardous waste reporting, and hazardous waste treatment and disposal. Refer to RCRA Online # 14949 for additional details about how the RCRA regulations apply to different types of generators, including generators that are operating under 40 CFR part 262 and healthcare facilities operating under 40 CFR part 266 subpart P.

RCRA Episodic Generation Option for Hand Sanitizer that is a Solid and Hazardous Waste

To reiterate from RCRA Online #14941, if hand sanitizer must be managed as hazardous waste, generators that are very small quantity generators (VSQGs) or small quantity generators (SQGs) may want to explore the possibility of disposing of the excess hand sanitizer under the episodic generator provisions of 40 CFR part 262 subpart L. These provisions allow a VSQG or SQG 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. Companies should check with their authorized state to determine if the episodic generation provisions are available in your state.

A healthcare facility or reverse distributor operating under 40 CFR part 266 subpart P for its hazardous waste pharmaceuticals (e.g., hand sanitizer) may not use the episodic generator standards of 40 CFR part 262 subpart L, with respect to its hazardous waste pharmaceuticals. Under part 266 subpart P, all healthcare facilities are regulated the same regardless of the amount of hazardous waste pharmaceuticals generated and all reverse distributors are regulated the same, regardless of amounts of hazardous waste pharmaceuticals managed, making the need for episodic generation provisions unnecessary. For additional detail about the intersection of the episodic generation provisions in part 262 subpart L and the standards for managing hazardous waste pharmaceuticals in part 266 subpart P, see the Hazardous Waste Pharmaceuticals Final Rule. 17

It should be noted that under RCRA, states regulations can be more stringent and/or broader in scope than the federal program, so we recommend checking with the appropriate state regulatory authority as well. If you have any other questions concerning this response, please contact Kristin Fitzgerald of my staff at Fitzgerald.Kristin@epa.gov or (202) 566-0512.

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¹⁷ February 22, 2019; 84 FR 5816 (page 5935).