



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

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United States Department of Agriculture
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Dear J. Kimberly Harriz:

Thank you for your e-mail and providing updates on the United States Department of Agriculture's (USDA's) activities and concerns on compliance issue on handling and disposal of hand sanitizer as our nation is recovering from the pandemic. The United States Environmental Protection Agency (USEPA) is actively engaged in addressing the issues and attached below are a few of the key highlights.

- **Chemical composition and Ignitability:** The chemical composition and ignitability characteristics of hand sanitizer are important criteria to determine its reclamation/recycling and disposal, and hand sanitizer products have a range of formulations.
 - **Composition:** Alcohol-based hand sanitizer typically contains at least 60% (volume/volume, v/v) alcohol (ethanol or isopropyl alcohol/isopropanol) in water and disinfectant (octenidine dihydrochloride and phenoxyethanol) (typical overall pH 6.5 - 7.5) (see **Figure 1** below). However, the composition could vary. World Health Organization (WHO) suggested general formulations: 1) ethanol (96 percent, %) and 2) isopropyl alcohol (99.8%). Final product concentration suggested by WHO for household or local production is ethanol (80%) v/v, hydrogen peroxide (0.125%) v/v and glycerol (1.45%) v/v for one of the formulation and isopropyl alcohol (75%) v/v, hydrogen peroxide (0.125%) v/v and glycerol (1.45%) v/v for another formulation.
 - **Flammability:** The alcohol-based hand sanitizing products are considered as flammable liquids¹ at room temperature by the Food and Drug Administration (FDA), the Federal Aviation Administration (FAA) and the Centers for Disease Control and Prevention (CDC) (flash point ~ 19 - 25 degree Celsius, °C) (FAA, 2010; CDC, 2019; Fedøy, 2021).

¹ The distinction between the properties 'flammability' and 'ignitability' can be defined in terms of temperature - for example, flammable mixtures at near ambient temperatures need considerations for fire safety, protection from sparks, flames and other localized sources of energy while chemicals could be not flammable but would ignite spontaneously if subjected to overheating.

- RCRA Hazardous Waste Ignitability Characteristic:** The USEPA's Resource Conservation and Recovery Act (RCRA) hazardous waste regulations (40 CFR 261.21[a][1]) stipulate that any liquid with a flashpoint below 140 degree Fahrenheit, °F (60 °C) is ignitable and therefore requires hazardous waste management, with the exception of aqueous solutions containing less than 24% alcohol (by volume). The RCRA hazardous waste code for ignitable hazardous waste is D001.
- Ignitability and Handling:** Alcohol-based hand sanitizers being discarded are classified as ignitable under RCRA. Containers holding ignitable materials need to be stored away from oxidizers, sources of ignition per the Fire Code. The container should be kept tightly closed in a cool, well-ventilated place. Ground container and transfer equipment to eliminate static electric sparks. Compliance with all national, state, and local codes pertaining to the storage, handling, dispensing, and disposal of ignitable liquids is required.
- Do Not Put It Down the Drain:** The Clean Water Act regulations prohibit the discharge of what would otherwise be classified as a RCRA D001 ignitable hazardous waste (see 40 CFR 403.5(b)).
- Do Not Put in the Trash bin or Garbage Pail:** RCRA hazardous wastes may not be disposed in the regular trash, unless the generator is considered a very small quantity generator (VSQG, see Volume Consideration for additional detail about VSQGs). And many states are more stringent and do not even allow VSQGs to put their hazardous waste in the trash.
- Reclamation/Recycling and Disposal:** Recycling of hand sanitizer could involve various salvaging processes to reclaim the alcohol from the hand sanitizer. 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. Hand sanitizer could also be used in fuel blending to get a new usable energy source. Certain hand sanitizers that are recalled because they do not meet the FDA's requirements would have to be managed in accordance with the FDA-approved recall strategy, which might include being returned to the manufacturer/pharmacy for proper disposal. As discussed above, the hand sanitizer wastes are considered a RCRA characteristic hazardous waste with the waste code D001 (unless tested to be otherwise). The RCRA regulations require the proper management, transportation, treatment, and disposal of the hazardous wastes, including the wipes and rags utilized to apply hand sanitizer (USEPA, 2021).
- Volume Consideration:** The RCRA hazardous waste regulations establish basic hazardous waste management standards for entities who produce hazardous waste, called hazardous waste generators. The detailed information on quantity limits including the amount of hazardous waste generated per month determines how a generator is categorized and the applicable regulations that must be complied with are available at Hazardous Waste Generator Regulatory Summary.

However, if the hand sanitizer has a "Drug Facts" label, it is considered a pharmaceutical when it is discarded. Healthcare facilities (including retailers) or reverse distributors must follow a different set of regulations (40 CFR Part 266 Subpart P) for the management of

hazardous waste pharmaceuticals. Subpart P is not in effect in all states; see the links to Hazardous Waste Programs and U.S. State Environmental Agencies and the [map](#) of where it is in effect. In states where Subpart P² is not in effect and for non-pharmaceutical uses, such as when isopropyl alcohol would not be labeled with “Drug Facts”, the hand sanitizers would be considered a non-pharmaceutical hazardous waste, and generators must manage the hand sanitizers under the hazardous waste generator regulations in 40 CFR Part 262.

Hazardous waste regulations provide an exemption for any amount of alcohol-based hand sanitizer that is returned to the manufacturer or to a recycler that can reclaim the material. If reclamation or return to the manufacturer is not available, a business that generates more than 100 kilograms (220 pounds) of hazardous waste in a calendar month, including alcohol-based hand sanitizer, must ensure the waste is transported under a hazardous waste manifest to an authorized hazardous waste disposal facility. Businesses that generate less than 100 kilograms per month of hazardous waste (Very Small Quantity Generators, VSQGs) may self-transport the hazardous waste to solid waste management facilities that are authorized to receive it. Generator of more than 100 kilograms per month are either Large Quantity Generators (LQGs) of hazardous waste, or SQGs (Small Quantity Generators) and there are cradle-to-grave management standards that apply to the hazardous waste. The level of regulation varies with the amount of hazardous waste that is generated in a calendar month. That is, LQGs have more regulations than SQGs. For SQGs, the total hazardous waste accumulation cannot exceed 6000 kilograms, including all other hazardous wastes in the area.

In contrast, under Subpart P, all healthcare facilities that generate above VSQG amounts of hazardous waste are regulated the same regarding the disposal of their hazardous waste pharmaceuticals. See the [Frequent Questions](#) to learn more about Subpart P.

In addition, the coronavirus pandemic triggered large volumes of hand sanitizer procurements. Many entities over-stocked and could not consume/manage the excess material. In addition to excess volume of material, certain hand sanitizers could not meet appropriate specification (for example, sanitizer manufactured outside of the United States (US) and/or failed to meet the FDA's standard for hand sanitizer products sold within the country) including not having an appropriate level of alcohol to be considered a hand sanitizer (a list of recalled or banned brands and products available at the [FDA updates on hand sanitizers consumers should not use](#)). There are warnings about hand sanitizer products that contain methanol, a substance often used to create fuel and antifreeze; and is not an acceptable active ingredient for hand sanitizer products (information and list of commodity ingredients [nonfood-use products] available at the [Pesticide Registration](#)). Additional issues could include odor, stickiness, presence of benzene, acetaldehydes, or other impurities. It is important to note that the surface disinfectants registered by USEPA are available at USEPA's [List N: Disinfectants for Use Against SARS-CoV-2](#) and information and guidance on alcohol-based hand sanitizer products available at the [FDA's website](#). Depending on the volume of FDA-recalled

² Subpart P does not apply to the management of non-hazardous pharmaceutical wastes, non-pharmaceutical hazardous wastes, or universal wastes.

hand sanitizer that an entity disposes, it may trigger the RCRA hazardous waste requirements.

In summary, when recycled, hand sanitizer is exempt from hazardous waste regulations and does not have to ship on a Uniform Hazardous Waste Manifest. If not recycled, the disposal of alcohol-based hand sanitizers requires full cradle-to-grave management, including (but not limited to) hazardous waste notification, hazardous waste labeling, manifesting, and waste reporting to the state or the federal government.

Thank you for your interest to this important matter. If you have additional questions, please contact Sandip Chattopadhyay of my staff at: chattopadhyay.sandip@epa.gov.

Sincerely,

Kim Kirkland

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