Temporary Policy for the Transportation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Notice of Enforcement Discretion U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration Office of Hazardous Materials Safety

April 10, 2020

I. INTRODUCTION

The U.S. Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety

Administration (PHMSA) plays a leading role in ensuring the safe transportation of hazardous materials throughout the United States by all modes. Because of the ongoing Coronavirus Disease 2019 (COVID-19) public health emergency, there has been a notable increase in the demand for products used for sanitization purposes – many of which contain alcohol and may be considered a hazardous material for transportation as defined by the Hazardous Materials Regulations (HMR, 49 CFR Parts 171-180). PHMSA is aware of multiple companies throughout the country that will be producing products such as hand sanitizer and other alcoholbased products to help respond to the COVID-19 public health emergency under specific FDA guidance. To facilitate the increased availability of products during this public health emergency, PHMSA intends to provide temporary relief from certain HMR requirements while continuing to maintain an appropriate level of safety for companies that are producing products under the FDA guidance. The relief provided herein is for the highway mode only. Shipments

by other modes of transportation must meet all requirements of the hazardous materials

regulations unless relief has been provided elsewhere.

II. BACKGROUND

As specified in the Food and Drug Administration's (FDA) guidance document "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry"¹, there is currently a public health emergency of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. In addition, on March 13, 2020, the President declared a national emergency

in response to COVID-19.

Hand hygiene is an important part of the U.S. response to COVID-19. Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the bathroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent ethanol or 70 percent isopropanol.

III. DISCUSSION

Alcohol-based products, such as hand sanitizers, are typically classified according to the HMR as a Class 3, Flammable Liquid. The HMR defines Flammable Liquids as a liquid having a flash point of 60 °C (140 °F) or below (see 49 CFR 173.120). The provisions of the HMR include

During the Public Health Emergency (COVID-19)". <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-during</u>

Docket #: FDA-2020-D-1106

¹ FDA "Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products

requirements applicable to classifying the material, selecting an appropriate packaging, and communicating the hazard through labeling, marking, placarding, and shipping papers. The requirements that apply vary depending on the concentrations of alcohol and the quantity and form of the product. For instance, 49 CFR § 173.150(g), Limited quantities of retail products *containing ethyl alcohol*, establishes provisions applicable to beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol. Specifically, these provisions apply to such products classed as a flammable liquid or flammable solid and containing not more than 70 percent ethyl alcohol by volume for liquids. Typically, hand sanitizers are transported in accordance with these provisions. If offered for

transportation in the quantities and packagings that are specified in § 173.150(g), hand sanitizers

are excepted from all other requirements of the HMR. During this public health emergency,

PHMSA is providing relief for additional packaging configurations and sizes to facilitate

transportation of these vital commodities from facilities operating under the FDA guidance.

RELIEF PROVIDED FOR THE TRANSPORTATION OF HAND SANITIZERS IV. PRODUCED IN ACCORDANCE WITH FDA GUIDANCE

PHMSA is providing the relief outlined below to companies that are producing hand sanitizer under the FDA guidance document referenced above to address the current COVID-19 public health emergency and companies that subsequently transport the hand sanitizer. PHMSA will not take enforcement action for violations of the hazardous materials regulations if the procedures below are followed.

A. SMALL QUANTITIES OF HAND SANITIZERS CONTAINING ETHYL ALCOHOL

OR ISOPROPYL ALCOHOL

This relief applies only to transportation by highway, and does not apply to shipments by air, vessel, or rail. Specifically, the procedures below apply to transportation of hand sanitizers by private, common, or contract carriers by motor vehicle. PHMSA will not take enforcement action for violations of the HMR when the following procedures are followed:

- 1. Packages contain hand sanitizer containing either ethyl alcohol or isopropyl alcohol at a concentration not to exceed 80 percent.
- 2. Packagings are leak tight and securely closed, secured against shifting, and protected against damage.
- 3. The material is contained in a packaging having a capacity not over 8 gallons.
- 4. For inner packagings not exceeding 1 gallon:
 - a. Packages are a combination package and the inner receptacle

containing the liquid is placed inside an outer packaging where the
inner packagings are secured and cushioned within the outer
packaging to prevent breakage, leakage, and movement and inner
packagings are packed with package closures in an upright
orientation.

- b. The net contents of all inner packagings in any single outerpackaging do not exceed 8 gallons (e.g., 8 x 1 gallon packages).
- c. The company name and the words "Sanitizer Contains Ethyl Alcohol" or "Sanitizer – Contains Isopropyl Alcohol" are marked on the outer package and, if applicable, the overpack. In addition,

the FDA label is acceptable as an alternative marking provided it is

visible in transportation. (See Appendix A through D of the FDA

Guidance at: https://www.fda.gov/media/136289/download)

- 5. Packages exceeding a capacity of 1 gallon:
 - a. Are overpacked in crates, cages, carts, boxes, or similar overpacks.
 - b. Packages are secured in the transport vehicle in such a way as to prevent breakage, leakage, and movement. Packages are packed with package closures in an upright orientation.
 - c. The company name and the words "Sanitizer Contains Ethyl Alcohol" or "Sanitizer - Contains Isopropyl Alcohol" is marked on

the outside of the single package and the overpack. In addition, the

FDA label is acceptable as an alternative marking provided it is

visible in transportation. (See Appendix A through D of the FDA

Guidance at: https://www.fda.gov/media/136289/download)

B. TRANSPORTATION OF LARGER QUANTITIES OF HAND SANITIZERS

PHMSA is aware that there may be a need to transport quantities greater than 8 gallons per package, for example, in drums or other packagings. To facilitate, PHMSA is providing relief from the existing provisions of the HMR. This relief applies for transportation by private or contract motor carrier, or common carrier in a vehicle under exclusive use for such service. This relief does not apply to shipments by air, vessel, or rail. PHMSA will not take enforcement action for failing to register with PHMSA irrespective of the quantity of hand sanitizer offered

for transportation or transported. In addition, PHMSA will not take enforcement action for

violations of the HMR for shipments of packagings containing more than 8 gallons but not more than 119 gallons of sanitizer, if the following procedures are followed:

- 1. The packaging contains hand sanitizer containing either ethyl alcohol or isopropyl alcohol at a concentration not to exceed 80 percent.
- 2. Packagings are leak tight and securely closed, secured against shifting, and protected against damage.
- 3. The material is contained in a packaging having a capacity not over 119 gallons.
- 4. The packaging must be DOT or United Nations (UN) specification packaging

(drums, jerricans, etc.) described in § 173.202 meeting the Packing Group

(PG) II performance standard.

- The packages are secured to prevent breakage, leakage, and movement during the course of transportation.
- 6. The registration requirements found in Subpart G of Part 107 will not apply.
- 7. Offerors and transporters of this material provide their employees handling this material with the applicable training materials prepared by PHMSA, in lieu of the training required by 49 CFR Part 172, Subpart H (see LINK).
- 8. Each package is labeled with a flammable liquid label (see § 172.419).
- 9. The bill of lading or shipping paper includes the following basic description "UN1987, Alcohols, n.o.s., Class 3, PG II" and indicate the number, type, and capacity of packages offered (for example, 25 drums – 119 gallons ea.).

10. A copy of the Emergency Response Guidebook Guide number 127 (attached)

accompanies the shipment.

11. If the aggregate gross quantity in a transport vehicle or freight containerexceeds 1,001 pounds, the vehicle is placarded as required by the HMR (see49 CFR Part 172, Subpart F for Placarding requirements).

12. All motor carriers comply with § 177.804.

V. WITHDRAWAL OF RELIEF

This Notice of Enforcement Discretion expires 3 months from its date of issuance or until the time when the public health emergency is over, whichever is sooner.

Issued on April 10, 2020, in Washington, D.C.

William S. Schoonover

Associate Administrator

For Hazardous Materials Safety

GUIDE 127 FLAMMABLE LIQUIDS (Polar / Water-Miscible)

POTENTIAL HAZARDS

FIRE OR EXPLOSION

- HIGHLY FLAMMABLE: Will be easily ignited by heat, sparks or flames.
- Vapors may form explosive mixtures with air.
- Vapors may travel to source of ignition and flash back.
- Most vapors are heavier than air. They will spread along ground and collect in low or confined areas (sewers, basements, tanks).
- Vapor explosion hazard indoors, outdoors or in sewers.
- Those substances designated with a P may polymerize explosively when heated or involved in a fire.
- Runoff to sewer may create fire or explosion hazard.
- Containers may explode when heated.
- Many liquids are lighter than water.

HEALTH

- Inhalation or contact with material may irritate or burn skin and eyes.
- Fire may produce irritating, corrosive and/or toxic gases.
- Vapors may cause dizziness or suffocation.
- Runoff from fire control may cause pollution.

PUBLIC SAFETY

- CALL Emergency Response Telephone Number on Shipping Paper.
- As an immediate precautionary measure, isolate spill or leak area for at least 50 meters (150 feet) in all directions.
- Keep unauthorized personnel away.
- Stay upwind.
- Keep out of low areas.
- Ventilate closed spaces before entering.

PROTECTIVE CLOTHING

- Wear positive pressure self-contained breathing apparatus (SCBA).
- Structural firefighters' protective clothing will only provide limited protection.

EVACUATION

Large Spill

Consider initial downwind evacuation for at least 300 meters (1000 feet).

Fire

If tank, rail car or tank truck is involved in a fire, ISOLATE for 800 meters (1/2 mile) in all directions; also, consider initial evacuation for 800 meters (1/2 mile) in all directions.

EMERGENCY RESPONSE

FIRE

CAUTION: All these products have a very low flash point: Use of water spray when fighting fire may be inefficient.

Small Fire

Dry chemical, CO2, water spray or alcohol-resistant foam.

Large Fire

- Water spray, fog or alcohol-resistant foam.
- Use water spray or fog; do not use straight streams.
- Move containers from fire area if you can do it without risk.

Fire involving Tanks or Car/Trailer Loads

- Fight fire from maximum distance or use unmanned hose holders or monitor nozzles.
- Cool containers with flooding quantities of water until well after fire is out.
- Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.
- ALWAYS stay away from tanks engulfed in fire.
- For massive fire, use unmanned hose holders or monitor nozzles; if this is impossible, withdraw from area and let fire burn.

SPILL OR LEAK

- ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area).
- All equipment used when handling the product must be grounded.
- Do not touch or walk through spilled material.
- Stop leak if you can do it without risk.
- Prevent entry into waterways, sewers, basements or confined areas.
- A vapor suppressing foam may be used to reduce vapors.
- Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.
- Use clean non-sparking tools to collect absorbed material.

Large Spill

- Dike far ahead of liquid spill for later disposal.
- Water spray may reduce vapor; but may not prevent ignition in closed spaces.

FIRST AID

- Move victim to fresh air.
- Call 911 or emergency medical service.
- Give artificial respiration if victim is not breathing.
- Administer oxygen if breathing is difficult.
- Remove and isolate contaminated clothing and shoes.
- In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.
- Wash skin with soap and water.
- In case of burns, immediately cool affected skin for as long as possible with cold water. Do not remove clothing if adhering to skin.
- Keep victim warm and quiet.
- Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Related Resources

• <u>Guide for Handling Household Chemicals</u> Things you can do to make your home safer.

USDOT Hazardous Materials Table 49 CFR 172.101

An online version of the USDOT's listing of hazardous materials from 49CFR 172.101. This table can be sorted by proper shipping name, UN/NA ID and/or by primary hazard class/division.

US DOT Hazardous Materials Transportation Placards

Hazardous materials placards (DOT placards) are required when shipping hazardous materials in the United States, Canada and Mexico. These pages provide US DOT definitions for each hazmat placard.

Chemical Database

This database focuses on the most common chemical compounds used in the home and industry.

PHMSA Hazardous Materials Information Center

Need clarification on an entry in the Hazardous Materials Regulations? PHMSA's Hazmat Information Center provides live, one-on-one assistance Monday through Friday from 9 a.m. - 5 p.m.

Call: 1-800-467-4922

Email: infocntr@dot.gov