U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

Safety Advisory Notice for the Transportation of COVID-19 Diagnostic Samples
U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Safety

The U.S. Department of Transportation (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) plays a leading role in ensuring the safe transportation of hazardous materials in commerce throughout the United States. Because of the ongoing Coronavirus Disease 2019 (COVID-19) public health emergency, there have been shipments of COVID-19 diagnostic samples (e.g., nasal swabs, vials of sputum, and other related items) that are classified as a Category B infectious substance (Division 6.2) hazardous material under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

Investigators from PHMSA's Office of Hazardous Materials Safety (OHMS) recently conducted compliance inspections and found several instances of improperly marked or packaged diagnostic samples that were offered for transportation, which included sample vials packaged without rigid outer packagings. In response, PHMSA has developed this Safety Advisory Notice to provide information on the HMR related to offering and transporting these materials.

Based on information we received from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), it is our understanding that human and animal specimen samples that are used to test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) should be classed and described as "UN3373, Biological substance, Category B, 6.2." A Category B infectious substance is a material known or reasonably expected to contain a pathogen in a form not generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. To ensure their safe transportation, SARS-CoV-2 diagnostic samples must be packaged and offered for transportation in conformity with the applicable requirements in the HMR for Category B infectious substances.

Triple Packaging

The packaging requirements for Category B infectious substances are prescribed in § 173.199 of the HMR. Under this section, Category B infectious substances must be properly triple-packaged, which means the diagnostic sample is first placed in a primary receptacle that is leakproof for liquids or siftproof for solids. The primary receptacle is then placed in a secondary leakproof or siftproof packaging. The secondary packaging is then placed in a rigid outer packaging.

The completed package must be designed, constructed, maintained, filled, and closed so that under conditions normal to transportation, there is no release of hazardous materials. Furthermore, the completed package effectiveness must not be substantially reduced by

temperature change, shock, pressure changes, and other conditions related to normal transportation.

Primary receptacles must be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. If several fragile primary receptacles are placed in the secondary package, they must be wrapped or separated to prevent contact between them. Secondary packagings, such as a biohazard bag, must be secured in rigid outer packagings. Furthermore, for liquid Category B infectious substances, there must be absorbent material placed between the primary receptacle and secondary package that is of sufficient quantity to absorb the total amount of liquid and not compromise the integrity of the cushioning material or outer packaging should the primary receptacle leak or break. For solid Category B infectious substances, the primary and secondary receptacles must be siftproof. If residual liquid may be present within the primary receptacle for a solid, or the solid may become liquid in transportation, the solid sample must be transported in conformance with § 173.199(b), the requirements for a liquid Category B material.

Package Capability Requirements

The completed package must also be capable of passing the drop test specified in § 178.609(d) of the HMR at a drop height of at least 1.2 meters (3.9 feet). Following the test, there must be no leakage from the primary receptacle, which must remain protected by the absorbent material, when required, in the secondary packaging.

Transport by Air

If the package is offered for transportation by aircraft, and the Category B infectious substance is liquid, the primary receptacle or the secondary packaging must be capable of preventing leaks by withstanding an internal pressure of not less than 95 kPa (0.95 bar, 14 psi). In addition, if a liquid Category B infectious substance is shipped by aircraft, the maximum quantity contained in each primary receptacle, including any material used to stabilize or prevent degradation of the sample, may not exceed 1 L (34 ounces), and the maximum quantity contained in each outer packaging, including any material used to stabilize or prevent degradation of the samples, may not exceed 4 L (1 gallon). If a solid Category B infectious substance remains solid and is shipped by aircraft, the maximum quantity contained in each outer packaging, including any material used to stabilize or prevent degradation of the samples but not including body parts, organs or whole bodies, may not exceed 4 kg (8.8 pounds). However, the outer packaging maximum quantity limit does not apply to ice, dry ice, or liquid nitrogen when these materials are used to maintain the integrity of the liquid or solid samples.

Required Markings

At least one side of the rigid outer packaging (usually a non-specification fiberboard box) must have a minimum dimension of 100 mm by 100 mm (3.9 inches). The package may not contain other hazardous materials except: refrigerants, such as dry ice or liquid nitrogen, as authorized under § 173.199(d); anticoagulants used to stabilize blood or plasma; or small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II and III used to stabilize or prevent degradation of the sample, provided the quantity of such materials does

not exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging. Such preservatives are not subject to the requirements of the HMR.

The following square-on-point mark must be displayed on the outer surface of the rigid outer packaging on a background of contrasting color. The width of the line forming the border must be at least 2 mm (0.08 inches) wide and the letters and numbers must be at least 6 mm (0.24 inches) high. The size of the mark must be such that no side of the diamond is less than 50 mm (1.97 inches) in length as measured from the outside of the lines forming the border. For domestic transportation, a packaging marked prior to January 1, 2017, and in conformance with the requirements of § 173.199(a)(5) in effect on December 31, 2014, may continue in service until the end of its useful life (see § 173.199(a)(5)(ii)).

The proper shipping name "Biological substance, Category B" must also be marked on the surface of the outer packaging adjacent to the diamond-shaped mark in letters that are at least 6 mm (0.24 inches) high.

Overpack Markings

When packages are placed in an overpack, such as a shipping bag, the text "Biological substance, Category B" and square-on-point "UN3373" marking must be either clearly visible or reproduced on the outside of the overpack.

Emergency Response Information

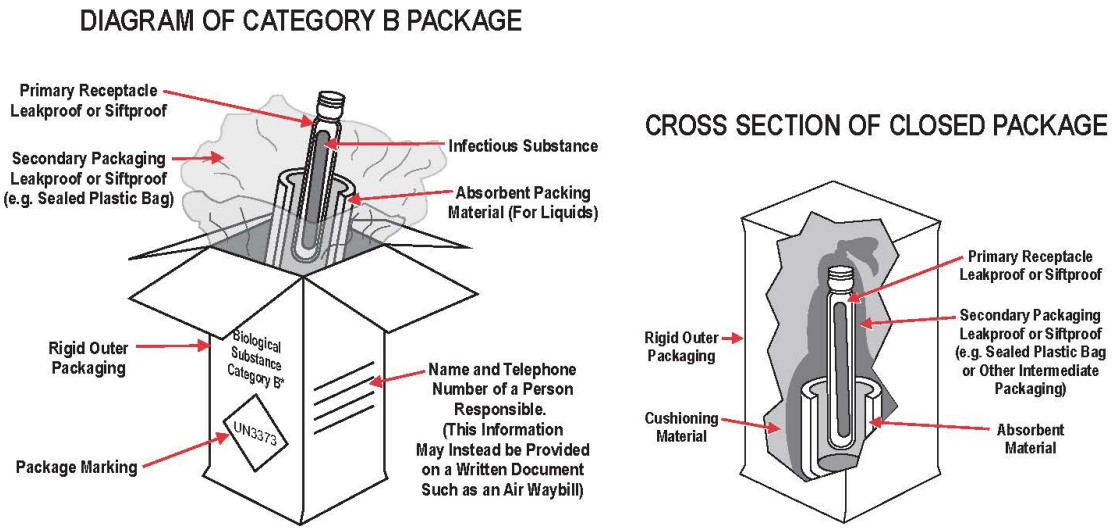
The package must also contain emergency contact information either displayed on a written document (such as an air waybill or bill of lading) or on the outer package. This emergency contact information must include the name and telephone number of a person who is either knowledgeable about the material being shipped and has comprehensive emergency response and incident mitigation information for the material or has immediate access to a person who possesses such knowledge and information.

Closure Instructions

Clear instructions on filling and closing a packaging used to transport a Category B infectious substance must be provided by the packaging manufacturer and subsequent distributors to the consignor or person who prepares the package to enable the package to be correctly prepared for transport. A copy or electronic image of these instructions must be retained by the manufacturer and subsequent distributors for at least one year from the date of issuance, and made available for inspection by a Federal or state government representative upon request. Packagings must be filled and closed in accordance with the information provided by the packaging manufacturer or subsequent distributor. Lastly, each person who offers or

transports a Category B infectious substance must know about the requirements of § 173.199 of the HMR.

Below is an example of the packaging required for Category B infectious substances:



Source: Transporting Infectious Substances Safely, PHMSA, Published April 2020: https://www.phmsa.dot.gov/training/hazmat/transporting-infectious-substances-safely

or

Source: Packaging and Shipping SARS CoV 2 Specimens, Cultures, Isolates and Waste, PHMSA, Published May 2020 https://www.phmsa.dot.gov/transporting-infectious-substances/packaging-and-shipping-sars-cov-2-specimens-cultures-isolates-and-waste

The HMR contain exceptions for Category B infectious substances that are based on maintaining a level of safety comparable to that provided for in the HMR (see §§ 173.6(a)(4) and 173.134(b) and (c)). These were developed over time in consultation with other federal and international health and/or transportation agencies, industry, and the regulated public.

This Safety Advisory Notice is intended only to provide clarity to the public regarding existing HMR requirements. The contents of this Notice do not have the force and effect of law, nor do they introduce new requirements binding the public in any way. It should not be used as a substitute for the HMR to determine compliance.

For further information on the offering for transportation or transporting infectious substances, see https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/Transporting-Infectious-Substances-Safely.pdf. For questions on the HMR requirements, please contact PHMSA's Hazardous Materials Information Center at telephone number 1-800-467-4922, from 9:00 AM to 5:00 PM Eastern Time.

Issued in Washington, D.C., on June 19, 2020.

William S. Schoonover,
Associate Administrator, Office of Hazardous Materials Safety
Pipeline and Hazardous Materials Safety Administration.