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Category B Infectious Substances

Infectious substance means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism that can cause disease in humans or animals. Examples of pathogens include bacteria, viruses, fungi, and other infectious agents. An infectious substance must be assigned to one of the following two packaging categories:

- Category A: Category A infectious substances are not mailable.
- Category B: An infectious substance that does not meet the criteria for inclusion in Category A. A mailpiece known or suspected to contain a Category B infectious substance is mailable as described in 346.

Proper Shipping Name and ID Number

- Biological substance, Category B, UN3373.

Required Authorization

All shippers of COVID-19 related UN3373 Category B Infectious Substances must obtain an authorization from the Postal Service prior to mailing. It is the responsibility of the shipper to ensure that they are aware of, and comply with, all other applicable requirements and regulations for the mailing of these materials; and they must be able to provide evidence of compliance before a written request is submitted to the manager of Product Classification, Postal Service Headquarters (see 214 for address).

Under these provisions, only tests developed and being performed by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) or equivalent clinical oversight regulations, and commercial tests and home collection kits authorized by either the FDA or an Institutional Review Board will be considered.

Mailability

- International Mail: Mailable only when:
  - Permitted by the destination country (see the Individual Country Listing in the IMM).
  - They are presented by and to authorized laboratories designated in “International Mail” below in this Packaging Instruction.
  - They meet the definition in 346.12a.
  - Written approval has been granted by the manager, Product Classification.
  - Quantity limits in 622.2 are met.
  - Sent via First-Class Package International Service with Registered Mail service.
- Domestic Mail: Mailable only when:
  - Intended for medical or veterinary use, research, or laboratory certification related to the public health.
  - Division 6.2 materials meet the preparation requirements for air transportation and sent via Priority Mail Express, Priority Mail, First-Class Mail, or First-Class Package Service.

Required Packaging

- Must be triple-packaged, meeting the packaging requirements in 49 CFR 173.199. Such materials must be properly packaged to withstand shocks, pressure changes, and other conditions related to ordinary handling in transit, and surrounded by absorbent material sufficient to protect the primary receptacle and to absorb the total amount of liquid should the primary receptacle leak or break.
- The completed triple packaging must be capable of successfully passing the drop test in 49 CFR§178.609(d) at a drop height of at least 1.2 meters (3.9 feet). Following the drop test, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging

Primary Receptacle (Container)

- Each primary receptacle containing a liquid must be leak proof. Each primary receptacle containing a solid must be sift proof.
- A single primary receptacle must not contain more than 1 liter (34 ounces) of a liquid specimen or 4 kg (8.8 pounds) of a solid specimen.
- Two or more primary receptacles whose combined volume does not exceed 4 liters (1 gallon) for liquids or 4 kg (8.8 pounds) for solids may be enclosed in a single secondary container.
- Only small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II and III may be 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.

Cushioning and Absorbent Material

- The space between the primary receptacle(s) and the secondary container at the top, bottom, and sides must contain enough material to absorb the entire contents of the primary receptacle(s) in case of breakage or leakage.
- Either the primary receptacle or the secondary container must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 0.95 bar, 14 psi (95 kPa), and temperatures in the range of –40° F to 131° F (–40° C to 55° C).

Secondary Container

- Secondary containers for liquids must be leak proof. Secondary containers for solids must be sift proof. The secondary packaging must be constructed of a durable material and have a secure sealing method.
- If the primary receptacle does not meet the pressure requirements listed above, then the secondary container must be designed to meet those requirements.
- The secondary container must be marked with the international biohazard symbol shown in Exhibit 346.321.

Note: Only cold packs or dry ice may be used as a refrigerant and must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary packaging in the original position. If cold pack is used, the packaging must be leak-proof. If dry ice is used, the outside packaging must permit the release

Outer Shipping Container

- The primary and secondary packaging must be enclosed in a rigid outer shipping container. The primary receptacle(s) and the secondary container must be enclosed in a strong outer packaging constructed of fiberboard or other equivalent material.
- At least one surface of the outer shipping container must have a minimum dimension of 3.9 inches by 3.9 inches (100 mm by 100 mm) as required by 49 CFR 173.199. The outer packaging must be of adequate size to accommodate all required shipping information and marks.

- A poly-type mailer bag covering may be acceptable as the outer packaging providing triple packaging is complete, the selvage edge of the wrapping is less than 2 inches, the required markings and address information are applied both on the interior rigid box and the additional outer polybag wrapping.

Markings

As required by 49 CFR 173.199:

- Each mailpiece (outer shipping container) must be marked on the address side with the proper shipping name "Biological Substance, Category B" and have the diamond marking indicating UN3373 (see Exhibit 346.12a2). The size of the mark on each side must not be less than 50 mm (1.97 inches) in length, the width of the border lines at least 2 mm, and letter and numbers must be at least 6 mm (0.24 inches) high.
- The address side of the outer shipping container must be marked with name and telephone number of a person who is knowledgeable about the material shipped and has comprehensive emergency response and incident mitigation information, or someone who has immediate access to the person with such knowledge and information.
- Orientation arrows are not required on these mailpieces but may be used.
- When dry ice is used, the package must include the markings "Carbon dioxide, solid" or "Dry ice" and an indication that the material being refrigerated is used for diagnostic or treatment purposes (e.g., frozen medical specimens). As this is the only information required with respect to global transportation regulations for dry ice included with UN3373 shipments, the requirements for dry ice as set forth in USPS Packaging Instruction 9A are not applicable.

Documentation

- Shippers must provide clear instructions to users regarding the procedures to be followed for preparing the samples and packaging used to transport a Biological Substance UN3373 Category B. Specific to COVID-19, shippers must instruct users to adhere to the required mailing preparation requirements including the sanitizing of external packaging, if applicable before mailing to enable the package to be safely prepared for transport.

International Mail

- Substances identified in IMM 135.11b *must* be sent *only* by authorized laboratories to their foreign counterparts in those countries that have indicated a willingness to accept them.

Note: Countries distinguish between infectious and noninfectious (nonregulated) biological substances and may prohibit one or the other or both. See "Prohibitions" in the Individual Country Listings.

- Infectious biological substances can be sent to or received by *only* the following types of institutions:
    a. Laboratories of local, state, and federal government agencies.
    b. Laboratories of federally licensed manufacturers of biological products derived from bacteria and viruses.
    c. Laboratories affiliated with or operated by hospitals, universities, research facilities, and other teaching institutions.

Private laboratories licensed, certified, recognized, or approved by a public authority.