

§ 173.196 Category A infectious substances.

(a) *Category A infectious substances packaging.* A packaging for a Division 6.2 material that is a Category A infectious substance must meet the test standards of §178.609 of this subchapter and must be marked in conformance with §178.503(f) of this subchapter. A packaging for a Category A infectious substance is a triple packaging consisting of the following components:

- (1) A watertight primary receptacle.
- (2) A watertight secondary packaging. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either wrapped individually or separated to prevent contact between them.
- (3) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must measure not less than 100 mm (3.9 inches) at its smallest overall external dimension.
- (4) For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.
- (5) An itemized list of contents enclosed between the secondary packaging and the outer packaging.
- (6) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).
- (7) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding without leakage temperatures in the range of $-40\text{ }^{\circ}\text{C}$ to $+55\text{ }^{\circ}\text{C}$ ($-40\text{ }^{\circ}\text{F}$ to $+131\text{ }^{\circ}\text{F}$).

(b) *Additional requirements for packaging Category A infectious substances.* Category A infectious substances must be packaged according to the following requirements, depending on the physical state and other characteristics of the material.

(1) *Infectious substances shipped at ambient temperatures or higher.* Primary receptacles must be made of glass, metal, or plastic. Positive means of ensuring a leakproof seal must be provided, such as heat seal, skirted stopper, or metal crimp seal. If screw caps are used, they must be secured by positive means, such as with adhesive tape, paraffin sealing tape, or manufactured locking closure. Lyophilized substances may also be transported in primary receptacles that are flame-sealed with glass ampoules or rubber-stoppered glass vials fitted with metal seals.

(2) *Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice, dry ice, or other refrigerant must be placed around the secondary packagings or in an overpack with one or more complete packages marked in accordance with §178.503 of this subchapter. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack must be leakproof. If dry ice is used, the outer packaging or overpack must permit the release of carbon dioxide gas and otherwise meet the provisions in §173.217. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used, as well as the temperatures and pressures of transport by aircraft to which they could be subjected if refrigeration were lost.

(3) *Infectious substances shipped in liquid nitrogen.* The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the liquid nitrogen as well as the temperatures and pressures of transport by aircraft to which they could be subjected if refrigeration were lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks vented to the atmosphere to prevent any increase in pressure within the packaging. The use of safety relief valves, check valves, frangible discs, or similar devices in the vent lines is prohibited. Fill and discharge openings must be protected against the entry of foreign materials that might cause an increase in the internal pressure. The package orientation markings specified in §172.312(a) of this subchapter must be marked on the packaging. The packaging must be designed to prevent the release of any refrigerated liquid nitrogen irrespective of the packaging orientation.

(c) Live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by

the Associate Administrator for Hazardous Materials Safety.

(d) Body parts, organs or whole bodies meeting the definition of Division 6.2 material must be packaged as follows:

(1) In Division 6.2 packaging, as specified in paragraphs (a) and (b) of this section; or

(2) In packaging meeting the requirements of §173.197.

[67 FR 53140, Aug. 14, 2002, as amended at 71 FR 32260, June 2, 2006]