

Packaging Requirements for Biological and Infectious Substances

General Guide

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Typically, air transport regulations are the most restrictive and the packaging specifications are the most rigorous. Shippers who comply with the air transport regulations also will meet the requirements of other transport modes. While there are some differences between the regulations for transport by air and by other modes (truck, rail, etc.), the vast majority of diagnostic specimens in the United States are packaged to comply with air transport requirements. Here, we have summarized the regulations of both the Department of Transportation (DOT) and the International Air Transport Association (IATA) into a single set of requirements. In cases where there are differences in meaning, we have used the more restrictive language.

If the hazardous materials you ship are UN 3373 “Biological substance, Category B,” “Diagnostic specimens,” “Clinical specimens,” or you ship medical or clinical waste, biological products, genetically modified micro-organisms, or other kinds of “infectious substances,” you should receive “General Awareness” hazardous materials training and “Infectious Substances” training. Those who prepare and ship specimens fitting the criteria for UN 3373 are required to know the requirements for proper transport.

What types of specimens meet the criteria of UN 3373?

“Diagnostic” or “clinical specimens”, or “Biological substance, Category B” are substances which are known or are reasonably expected to contain pathogens and which are shipped for diagnostic or investigational purposes. Pathogens are defined as micro-organisms and other agents which can cause disease in humans or animals. Such pathogens are divided in two categories – A and B.

Category A

The pathogens listed in Category A present the greatest hazards to individuals and communities; and must be assigned and transported in compliance with 49 CFR, Part 173.196 or IATA Packing Instruction 602. They must be identified as either “UN 2814 Infectious substance, affecting humans” or “UN 2900 Infectious substance, affecting animals.” If exposure occurs, an infectious substance is capable of causing permanent disability, life-threatening or fatal disease to humans or animals.

Category B

Human or animal specimens which do not contain pathogens in Category A fall into Category B; and must be assigned to UN 3373 “Biological substance, Category B.” All UN 3373 substances must be transported in compliance with 49 CFR, Part 173.199 or IATA Packing Instruction 650.

Transport Packaging for UN 3373 Substances

Any packaging for biological substances must include three components:

- A primary receptacle: the tube, vial or other container typically made of glass or rigid plastic (including the stopper, cap or other closure elements) that is in direct contact with the specimen.
- A secondary packaging (including cushioning and other materials) that fully encapsulates the primary receptacle.
- An outer packaging for shipping or transit.

Components must meet specific requirements, including being capable of passing specific test procedures based on receptacle or packaging type. In addition, compliance with the regulations is based, in part, on overall performance; so there can be no substitutions of a component from one manufacturer with a similar – but untested – component from another manufacturer.

Component Requirements:

- Under normal conditions of transport, primary receptacles must not break or leak their contents into secondary packagings.
- Multiple primary receptacles in the same secondary packaging must be separated to prevent contact between them.
- The performance of cushioning materials and the outer packaging must not be compromised due to any leakage from primary receptacles.
- For liquids, absorbent material sufficient to absorb the entire contents of all primary receptacles must be placed between the primary receptacles and the secondary packaging.
- One external surface of the outer packaging clearly must show the text “BIOLOGICAL SUBSTANCE, CATEGORY B.” Adjacent to this, inside a diamond mark whose lines are at least 2 mm thick, must appear the text “UN 3373” in characters at least 6 mm high.

Requirements for use of Ice, Dry Ice (carbon dioxide, solid), and Liquid Nitrogen as refrigerants for diagnostic or clinical specimens in transport:

- The primary receptacle(s) and secondary packaging must maintain their integrity and performance at the temperatures of the refrigerant used as well as at the temperatures and pressures that could result if refrigeration were lost.
- If ice or dry ice is used, it must be placed outside the secondary packaging, inside the outer packaging, or in an overpack. Also, the secondary packaging must be supported internally so that it maintains its original position while the ice melts or dry ice sublimates.
- If ice is used, the outer packaging must be leakproof and its performance must not be compromised by leakage of water.
- If dry ice is used, the packaging must allow for escape of carbon dioxide gas. In addition, the outer packaging must be marked with the text “Dry Ice” or “Carbon dioxide, solid” and “UN 1845” and the net quantity, in kilograms, of dry ice. Finally, these markings must be accompanied by the Class 9 label for Miscellaneous Dangerous Goods.
- When dry ice or liquid nitrogen is used, all other applicable requirements of the hazardous materials regulations must be met.

Please review IATA Packing Instructions 602 and 650 for the complete guide of packaging requirements.