Packing and Shipping Guidance for Biological Substances, Category B Specimens



All Category B specimens must be packed, labeled and documented according to the US Department of Transportation (DOT) Hazardous Material Regulations (HMR) 49 CFR § 100-185

CATEGORY B SPECIMEN TRIPLE PACKAGING REQUIREMENTS (49 CFR §173.199)

1 Primary Container

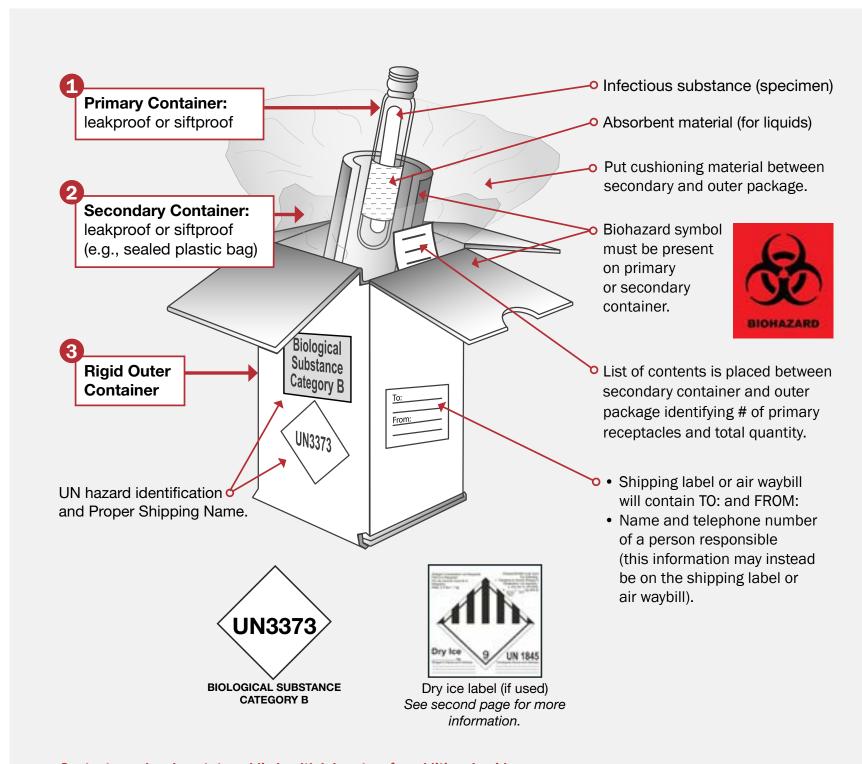
- Specimen(s) are placed in a sealed leakproof (for liquids) or siftproof (for solids) container.
- For liquids, the quantity must not exceed 1 L.
- Recommended best practice: The primary container lid has an additional secure closure by secondary means for liquids (e.g., tape or parafilm).

Secondary Container and Packaging

- Primary container(s) are placed in a sealed leakproof or siftproof secondary container.
- Absorbent material is placed between primary and secondary containers and is sufficient to absorb the entire quantity of a liquid hazardous substance.
- A list of contents is placed between the secondary container and outer package (e.g., number of samples, liquid vs. solid, total hazardous quantity).
- A biohazard symbol must be present on either the primary or secondary container.

Rigid Outer Container

- Secure secondary container inside the rigid outer packaging and use additional cushioning to secure secondary packaging, if needed.
- Outer packaging is securely closed and must not exceed 4 L (for liquids) or 4 kg (for solids).
- At least one surface must have a minimum dimension of 100 mm x 100 mm (3.9 inches).
- Outer Packaging is marked with UN3373 placed on one side of package in the form of a square set at an angle of 45° (diamond shaped) with each side having a length of at least 50 mm, the width of the line at least 2 mm and the letters at least 6 mm high.
- Outer packaging is marked with the proper shipping name: "Biological Substance, Category B" adjacent to UN3373.
- Name and address of the shipper and consignee (recipient) must be listed.
- Orientation arrows are on opposing sides if shipping liquids.
- Name and phone number of responsible person must be listed on outer package, a shipping label, or on an air waybill if used. This must be someone 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. The phone number must be monitored during normal business hours.



Contact your local or state public health laboratory for additional guidance: www.aphl.org/membership/Pages/memberlabs.aspx

Additional Category B Information and Resources

Category B Specimens:

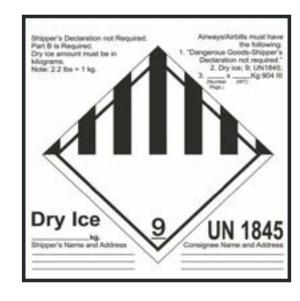
Category B specimens are infectious substances not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Most specimens shipped by clinical laboratories for diagnostic testing purposes may be classified as Biological Substances, Category B. Common examples of Category B specimens include COVID-19 swabs, *Salmonella* isolates, animals for rabies testing, and blood for HIV or hepatitis testing.

CATEGORY B TRAINING REQUIREMENTS (49 CFR §172.704)

- General awareness/familiarization of the US Department of Transportation (DOT) Hazardous Materials Regulations (HMR 49 CFR § 100-185).
- Function specific training (according to what duties the employer assigns).
- Safety training (e.g., proper handling of infectious substances, OSHA Bloodborne Pathogens, etc).
- Security awareness training.
- In-depth security training if subject to security plan requirements (e.g., if a laboratory has a CDC registered Select Agent Program).
- Employer authorization/certification to package and ship infectious substances.

Refrigerants

- Specimens must already be at desired temperature (e.g., frozen or refrigerated) prior to placing in box for transport.
- If shipping specimens at refrigerated temperature (2-8 °C), include frozen ice packs or gel packs outside of secondary container, add extra absorbent material, and note temperature handling conditions on rigid outer packaging.
- If shipping specimens at frozen temperature (<0°C), include dry ice outside of secondary container, add extra absorbent material, and note temperature handling conditions on rigid outer packaging.
- If dry ice is included:
 - » Rigid outer packaging must not be sealed tightly and must permit the release of carbon dioxide gas.
 - » Packaging must maintain integrity and temperature.
 - » Rigid outer packaging must be marked with Class 9 miscellaneous dangerous goods label, the proper shipping name: "Dry Ice", the UN1845 hazard identification, and the quantity included in kg. Place label on same side of box as UN3373 label.
 - » Note inclusion of dry ice on air waybill or Shipper's Declaration for Dangerous Goods if either are used.



NOTES FOR CATEGORY B:

- Use all triple packaging according to the manufacturer's instructions.
- UN certified packaging is not required.
- A Shipper's Declaration of Dangerous Goods is not required for Category B shipments.
- For liquids shipped by air, either the primary or secondary container must be capable of withstanding, without leakage, an internal pressure differential of not less than (<) 95 kPa (0.95 bar, 14 psi).
- Package must be capable of withstanding a 1.2 meters (3.9 ft) drop test (49 CFR § 178.609(d)).
- Adhere to the mode of transport and any additional carrier or courier requirements:
 - » Ground Transport: 49 CFR § 173.199
 - » Air Transport: IATA, Packing Instruction 650

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