Packaging Requirements to Transport Biological Substances & Hazardous Materials

Manual

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The International Air Transport Association (IATA) Dangerous Goods and U.S. Department of Transportation (DOT) regulate shipment of hazardous substances including infectious substances and chemicals including:

- Category A
- Category B
- Patient/Animal Specimens
- Biological specimens containing chemical preservatives such as ethanol, formaldehyde or formalin
- Dry ice

The following substances are not required to follow the IATA or DOT regulations:

- Materials that do not contain pathogens or only contains inactivated or neutralized pathogens (biological specimens contain chemical preservatives)
- Environmental samples that do not pose a significant threat of infection (i.e., food, water soil or dust samples)
- Dried blood spots, or fecal occult screening tests
- Blood or blood components collected for the purpose of transfusion
- Tissue or organs used for transplantation
- Patient Specimens

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Minimum Requirements for Securing Biological Substances and Hazardous Materials

Reduce the possibility of unauthorized access, possession, and use of hazardous materials by securing all hazardous materials, including dry ice. The following general guidelines represent minimum requirements:

- Limit information concerning hazardous materials shipments to authorized employees, carrier personnel, and supervisors. Do not share information on dangerous goods shipments with casual acquaintances or strangers.
- Limit access to areas where dangerous goods packages or other hazardous materials are prepared for shipment, received, stored, unpacked, or used to authorized employees only.
- Packages containing dangerous goods must be kept in a secure area, or under the supervision of a designated shipper, or other authorized employee(s) until picked up by the carrier.
- Make sure the carrier picking up dangerous goods shipments has identification (e.g. company ID, uses a clearly identified company vehicle, or wears a company uniform).
- Report suspicious individuals and behavior, stolen or missing hazardous materials and/or hazardous materials packages, and known or suspected unauthorized entry into secured areas to your supervisor and to the Department of Public Safety.
- Report latches and locks on doors or other security devices that are damaged, or evidence of being tampered to your supervisor and the Department of Public Safety.
- Be aware of your surroundings; look for out-of-place vehicles and abandoned or out-of-place backpacks, bags, or other containers.
Classification Guide for Infectious and Biological Substances

Does the substance contain pathogens?
  No: Your shipment is not subject to DOT/IATA Shipping Regulations
  Yes: Was the substance collected for the purpose of transfusion or transplantation?
    No: Is it a dried blood spot or fecal occult screening test?
      No: Are you shipping a Patient Specimen unlikely to contain pathogens?
        Yes: Ship as Patient Specimen
        No: May it contain an infectious substance that when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. *
          Yes: Category A: Contact EHS-Biosafety@umich.edu
          No: Infectious Substance, Category B: UN 3373. Use PI 650
Category A Infectious Substances

Category A substance: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with human or animals.

**NOTE:** Laboratories planning to ship Category A infectious substances **must** contact Biological Safety at (734) 647-1143 or EHS-Biosafety@umich.edu for instructions for packing and shipping the Category A infectious substance.

**Examples**

For examples of Category A infectious substances, refer to the [IATA Dangerous Goods Regulations](#).

**Identification**

- UN 2814: Human or both humans and animals
- UN 2900: Animals only

Category B Infectious Substances

A Category B substance is an infectious substance which does not meet the criteria for inclusion in Category A. This can be human, animal, bacterial, viral, or fungal material transported for research, diagnosis, disease, or treatment.

**Cultures**

In addition to Category B infectious substances, cultures **must** be shipped following the IATA Dangerous Goods regulations. Cultures are defined as the result of a process by which pathogens are intentionally propagated.

**NOTE:** This definition does not include patient specimens (for example, throat swabs) intended for diagnostic purposes.

**Proper Shipping Names and UN Numbers**

- Biological Substance, Category B: UN Number: UN 3373
- Dry Ice
  - UN 1845 Dry Ice
  - UN 1845 Carbon Dioxide, solid

**IATA/DOT Packing Instructions**

Category B infectious substances and cultures **must** be packaged using the IATA/DOT Requirements for Packing Instructions (PI) 650.

**WARNING:** Using the incorrect packing materials, package, and labels can cause the package to be out of compliance.
Labels
The following labels **must** be on the vertical side of the outer package when shipping Category B Substances:

<table>
<thead>
<tr>
<th>LABEL</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Shipper/Responsible Party Label" /></td>
<td>Shipper/Responsible Party Label</td>
</tr>
<tr>
<td><img src="image" alt="UN3373 label" /></td>
<td>UN3373 label</td>
</tr>
<tr>
<td><img src="image" alt="Orientation label" /></td>
<td>Orientation label</td>
</tr>
<tr>
<td><img src="image" alt="Shipper and Receiver Address label" /></td>
<td>Shipper and Receiver Address label</td>
</tr>
<tr>
<td><img src="image" alt="Class 9 Miscellaneous Dangerous Good label" /></td>
<td>Class 9 Miscellaneous Dangerous Good label</td>
</tr>
</tbody>
</table>

**NOTE:** This label **must** be on the outside of the package or on the air waybill.

**NOTE:** The outer package **must** bear two labels or one combined label.

**NOTE:** Use this label for shipments that include more than 50 mL of liquid.

**NOTE:** An orientation labels **must** be placed on two opposite sides of the package. The arrows **must** be oriented with the primary receptacles.

**NOTE:** All packages containing dry ice **must** have these two markings in one of the following formats:
- Separate class and UN label
- A label containing both the class and UN number

The class label and the UN number handwritten on the package.
Exempt and Unregulated Specimens

Patient and animal specimens for which there is minimal likelihood that pathogens are present are not subject to the Dangerous Goods regulations.

Exempt Specimens

Exempt specimens do not contain infectious agents or are not know to contain infectious agents. There are two kinds of exempt specimens:

- Exempt Human Specimens
- Exempt Animal Specimens

The specimens collected including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment, or prevention.

Unregulated Specimen Examples

Examples of unregulated specimens, which may be transported:

- Non-pathogenic genetically modified organisms and microorganisms.
- Organisms or microorganisms that have been purposely altered through genetic engineering in a way that does not occur naturally.
- Not regulated when transported by ground within the US.

**NOTE:** Some non-pathogenic genetically modified organisms and microorganisms are Class 9 Dangerous Goods when shipped outside the US.

- Substances with no probability or a low probability of containing an infectious substance including:
  - Wild type microorganisms that do not cause disease in humans or animals
  - Dried blood spots, specimens for fecal blood detection
  - Substances that have been treated so that pathogens have been neutralized
  - Blood, blood components, tissues or organs collected for transfusion or transplantation
  - Foodstuff or environmental samples (water, dust, mold)

Determining if the Specimen is Exempt

Use the following criteria to determine if a specimen is exempt from IATA and DOT regulations:

- **Specimen must** be taken directly from a patient or animal
- Professional judgment has been made to determine the sample does not contain an infectious substance:
  - No local outbreaks of infectious disease at the time of extraction
  - Patient displays no symptoms of infectious disease
  - Medical history does not indicate pre-existing infectious disease
  - Specimen has minimal likelihood of containing a pathogen
Labels

The following labels **must** be on the vertical side of the outer package when shipping human or animal specimens:

<table>
<thead>
<tr>
<th>LABEL</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Shipper and Receiver Address label" /></td>
<td>Shipper and Receiver Address label</td>
</tr>
<tr>
<td><img src="image" alt="Exempt Human Specimens and Exempt Animal Specimens combined label" /></td>
<td>Exempt Human Specimens and Exempt Animal Specimens combined label</td>
</tr>
<tr>
<td><img src="image" alt="Class 9 Miscellaneous Dangerous Good label" /></td>
<td>Class 9 Miscellaneous Dangerous Good label</td>
</tr>
</tbody>
</table>

**NOTE:** All packages containing dry ice **must** have these two markings in one of the following formats:

- Separate class and UN label
- A label containing both the class and UN number
- The class label and the UN number handwritten on the package
Genetically Modified Micro-Organisms and Genetically Modified Organisms

IATA specification 3.9.2.5.1 states genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs) are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Shipping Regulations

GMO and GMMO must be assigned to UN3245 if they meet the definition above (DGR 3.9.2.5.1) and are not toxic or infectious (by their definitions).

GMO and GMMOs are not subject to the Dangerous Goods Regulations when they are approved for use in the States of origin, transit, and destination.

Proper Shipping Names and UN Number

- Genetically modified organism (shipped internationally)
  - UN 3245 Genetically modified organism
  - UN 3245 Genetically modified microorganism
- Dry Ice
  - UN 1845 Dry Ice
  - UN 1845 Carbon Dioxide, solid

IATA/DOT Packing Instructions

GMMO and GMO assigned UN3245 must be packaged using the IATA/DOT Requirements for Packing Instructions (PI) 959.

WARNING: Using the incorrect packing materials, package, and labels can cause the package to be out of compliance.

Labels

The following labels must be on the vertical side of the outer package when shipping GMMOs or GMOs:

<table>
<thead>
<tr>
<th>LABEL</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Person Responsible Label" /></td>
<td>Shipper/Responsible Party Label</td>
</tr>
<tr>
<td><img src="image" alt="UN3245 Label" /></td>
<td>UN3245 label</td>
</tr>
</tbody>
</table>

**NOTE:** This label must be on the outside of the package or on the air waybill

**NOTE:** For packages being shipped internationally, the outer package containing GMMOs or GMOs must bear both labels.
**LABEL**

<table>
<thead>
<tr>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipper and Receiver Address label</td>
</tr>
<tr>
<td>Orientation label</td>
</tr>
<tr>
<td>Class 9 Miscellaneous Dangerous Good label</td>
</tr>
<tr>
<td>Dry Ice UN 1845 label</td>
</tr>
</tbody>
</table>

**NOTE:** Use this label for shipments that include more than 50 mL of liquid

**NOTE:** An orientation label **must** be placed on two opposite sides of the package. The arrows **must** be oriented with the primary receptacles.

**NOTE:** All packages containing dry ice **must** have these two markings in one of the following formats:
- Separate class and UN label.
- A label containing both the class and UN number.
- The class label and the UN number handwritten on the package.

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**Biological Specimen Containing Chemical Preservatives**

Biological specimens that contain chemical preservatives such as ethanol, formaldehyde, or formalin are regulated hazardous materials by U.S. DOT and IATA, and they can be shipped in small quantities. Hazardous materials are generally defined as any substance that could adversely affect the safety of the public, handlers, or carriers during transportation. Shipments of hazard materials **must** be packaged, marked, and accompanied by a dangerous goods declaration.

Certain materials are exempt from shipping requirements when shipped in small quantities. These materials may be shipped as "Dangerous Goods in Excepted Quantities" with an “Excepted Quantities” label instead of completion of a Dangerous Goods declaration.

**NOTE:** Infectious substances are **not** included in this provision.
The following table defines the chemical preservatives that are exempt from shipping requirements and the information needed to label and mark the packages:

<table>
<thead>
<tr>
<th>CHEMICAL PRESERVATIVE</th>
<th>EXCEPTED QUANTITIES</th>
<th>UN NUMBER*</th>
<th>CLASS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol-- A solution containing more than 24% ethanol by volume.</td>
<td>Small quantities (inner container less than 30 ml, with a maximum net quantity of 500 ml for the entire package) of ethanol</td>
<td>UN1170</td>
<td>3</td>
</tr>
<tr>
<td>• Formaldehyde (More than 25%)</td>
<td>Small quantities (inner container less than 30 ml, with a maximum net quantity of 1 L for the entire package) of formalin/formaldehyde</td>
<td>• Formaldehyde: UN2209</td>
<td>• Formaldehyde: 8</td>
</tr>
<tr>
<td>• Formalin (At least 3.7% but less than 25% formaldehyde)</td>
<td></td>
<td>• Formalin: UN3344</td>
<td>• Formalin: 9</td>
</tr>
</tbody>
</table>

*Must be included on the Excepted Quantity label.

**Documentation**

The "Nature and Quantities of Goods" box on the air waybill (invoice) **must** be completed with the words: "Dangerous Goods in Excepted Quantities".

**Packaging**

Use well-constructed packaging to cushion the inner containers and enough absorbent material to absorb the entire contents of the inner packages should they break open during transport. Inner containers can be glass or plastic with the closure held securely in place (taped closed). The outer container can be a cardboard box.

**Labels**

When shipping formaldehyde or formalin, use the **Excepted Quantity label**. It is best to print it onto an adhesive backed label.

It **must** be:

- Printed using a color printer
- No smaller than 100mm by 100mm
- Placed on the vertical side of the outer package

**Packaging Requirements for Category B, Exempt, Unregulated, and Genetically Modified Substances**

The following biological substances **must** be placed in three different packages when being transported or shipped to a new location:

- Category B
- Exempt and unregulated
- Genetically modified micro-organisms, and genetically modified organisms
The three types of packaging are discussed in the following table:

<table>
<thead>
<tr>
<th>PACKAGING</th>
<th>MAXIMUM VOLUME (AMOUNT)</th>
<th>EXAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>A leak proof primary receptacle</td>
<td>1L/primary receptacle</td>
<td>• Cryovial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Test tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Eppendorf tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Petri plate (inside a ziplock bag)</td>
</tr>
<tr>
<td>A leak proof secondary packaging</td>
<td>Liquid: 4L or 4Kg/package</td>
<td>• Sealed plastic ziplock bag</td>
</tr>
<tr>
<td></td>
<td>Solid: 4Kg/package</td>
<td>• Sealed plastic containers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Conical tubes</td>
</tr>
<tr>
<td>Outer packaging</td>
<td>Insulated cooler</td>
<td></td>
</tr>
</tbody>
</table>

Use well-constructed packaging to cushion the inner containers and enough absorbent material to absorb the entire contents of the inner packages should they break open during transport. Inner containers can be glass or plastic with the closure held securely in place (taped closed). The outer container can be a cardboard box.

Packages may be re-used if they are in good condition and have been disinfected. If packages are used for items other than infectious substances, all labels and marks for infectious substances must be removed or completely covered.

**WARNING:** Using the proper packing materials, package, and labels incorrectly can cause the package to be out of compliance.

**Primary Receptacle Requirements**

Primary receptacles must be able to be secured with a lid or sealed with a screw top lid or with tape or parafilm. Each of the containers must have the container’s content, hazards, and ownership on or with the container.

**Secondary Packaging Requirements**

When placing multiple primary glass receptacles in the same secondary package, each primary glass receptacle must be wrapped or separated from each other. This will prevent them from breaking or becoming damaged during transport.

The secondary package must be sealed so that it will not open and spill the contents during transport.

**Outer Container Requirements**

To prevent a release or leak of the infectious substance, place absorbent material between the primary containers and secondary package. Use enough absorbent material to absorb the entire contents of the primary containers if they should break.

In addition, the secondary package must fit in the outer package, and it must fit as close as possible to prevent the secondary package from moving too much during transport.
The outer container **must**:

- Be capable of surviving a drop test at a height of 1.2 meters without leakage from the primary receptacle. The primary receptacles **must** remain protected in the secondary packaging.  
  **NOTE:** A manufacturer’s drop test includes a water spray of 5 cm/hour for at least one hour and storing the packaging in an atmosphere of -18 C for 24 hours.
- Be adequate in strength
- Have a secure lid (e.g., plastic box, insulated cooler).
- Be rigid so as to retain its original shape and dimensions at all times under all conditions of transportation.
- Have at least one surface with a minimum dimension of 100mm X 100mm (4 inches x 4 inches).
- Allow the secondary container to fit as closely as possible to prevent excessive movement during transport which could damage the primary containers.  
  **NOTE:** If there is space between the secondary container and outer container, place padding between the two containers to prevent the inner container from shifting.

**Refrigerants**

All refrigerants **must** be placed outside the secondary packaging.

- Gel packs: Use gel-packs in place of wet ice. There are no requirements for marking or labeling the outer package for use of gel packs.  
  **NOTE:** It is difficult to achieve and maintain lower temperatures using gel packs.
- Dry ice: Class 9 Dangerous Good  
  **NOTE:** For instructions about to ship dry ice, refer to the section [Packaging Requirements for Dry Ice](#).

**Markings**

Markings refer to the information on the outer package and airway bills.

- The marking **must** be 2 inches by 2 inches minimum
- A diamond marking with the appropriate UN number
- The proper shipping name to the marking
- The name, address and phone number of a responsible person **must** be on the air waybill or marked on the package.
- If an airway bill is used, the “Nature and Quantity of Goods” box **must** show the text “Biological Substance, Category B” and “UN 3373”.

**Packaging Requirements for Dry Ice**

Dry ice is a hazardous material and is regulated by both the U.S. Department of Transportation (DOT) and the International Air Transport Association (IATA). Specific procedures are required for handling, packaging, and shipping materials refrigerated with dry ice. In addition the information in this document, refer the IATA/DOT Requirements for Packing Instructions (PI) 904 and the document [ACCEPTANCE CHECKLIST FOR DRY ICE](#) for more information.
Communication
- Contact the carrier to ensure proper ventilation will be available for the package and to determine if the carrier has additional requirements from those specified in the PI 904
- Coordinate logistics of the shipment with the recipient. Take into account local holidays or closings that might delay package receipt.

Dry Ice Amount
Refer to package manufacturer’s recommendations to determine the correct amount of dry ice to include in your shipment.

The actual time will vary depending on the package used and the volume and density of the dry ice. In general, however, dry ice will sublimate from a solid to a gas at a rate of 5-10 pounds (2.27-4.54 kg) per 24 hours when shipped in an appropriate insulated cooler.

Package Information
Use commercially available packaging systems intended for dry ice. Do not use plastics that can be rendered brittle or permeable by the temperature of dry ice. The package used to ship dry ice must be:

- Insulated
- Capable of venting gas to prevent the build-up of pressure
- Free from damage and of adequate strength for intended use
- Strong enough to withstand the loading and unloading normally encountered in transport
- Constructed and closed in order to prevent any loss of contents that might be caused by vibration or changes in temperature, humidity or altitude

You may choose to reuse a dry ice shipping box for future shipments. However:

- Deface all markings, labels, addresses, barcodes and carrier labels on the box
- Use caution if reusing a box that had previously been used for shipments of infectious substances or diagnostic specimens. Only reuse a box if you can personally verify it is not contaminated and its integrity is intact.
Packing Instructions

- Never seal dry ice in a container with an airtight seal such as a container with a threaded lid, ziplock bag, or cooler
- Place the dry ice outside the sealed primary and secondary receptacles
- Secure the secondary packaging such that the original orientation of the primary receptacle is maintained after the dry ice melts
- Add additional packing materials such as peanuts or crumpled paper (to minimize the volume of air to which the dry ice is exposed in order to slow the rate of sublimation)
- Pack the insulated package in outer cardboard box
- Tape ONLY the center of the cardboard box where the flaps meet on top of the box

UPS Packaging Quantity Limits

Packages must not contain more than 200 kg of dry ice.

<table>
<thead>
<tr>
<th>PACKAGES CONTAINING...</th>
<th>REQUIREMENT...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry Ice</td>
<td>Less than the total weight of the shipment</td>
</tr>
<tr>
<td>Substances or Materials for diagnostic or medical purposes</td>
<td>UPS “Blue Label”</td>
</tr>
<tr>
<td>Non-medical substances or non-hazardous materials</td>
<td>2.5 kg (5.5 pounds or less)</td>
</tr>
<tr>
<td></td>
<td><strong>NOTE</strong>: If greater than 2.5kg (5.5 pounds) a separate UPS hazardous material agreement is required. Contact UM Procurement for additional details.</td>
</tr>
</tbody>
</table>
Carrier’s Airbill

The carrier’s airbill must include the statement “Dry ice, Class 9, UN1845, number of packages X net weight of dry ice in kilograms.

Federal Express (FedEx) has a check box on their airbill to satisfy this requirement. Other carriers use slightly different formats. Airbill’s created electronically must include the same information. Check the airbill to ensure this information is included prior to sending shipment.

<table>
<thead>
<tr>
<th>SECTION</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Ship “From” and “To” Information</td>
</tr>
<tr>
<td>B</td>
<td>Priority Service</td>
</tr>
<tr>
<td>C</td>
<td>Packaging</td>
</tr>
<tr>
<td>D</td>
<td>Special Handling</td>
</tr>
<tr>
<td>E</td>
<td>Nature and Quantity of Goods</td>
</tr>
</tbody>
</table>
IATA/DOT Marking and Labeling Requirements
The outermost container must be labeled with a hazard Class 9 Miscellaneous Dangerous Good label, UN 1845, and net weight of dry ice in kilograms.

![Class 9 UN 1845 Label]

Additional Carrier Requirements
FedEx has no additional restrictions for shipping dry ice.

UPS requires the UPS Blue Dry Ice label in addition to the IATA/DOT requirements for marking and labeling:

![UPS Blue Dry Ice Label]

Shipment of dry ice and other dangerous goods without an approved contract with UPS are prohibited. Shippers must establish contracted services with UPS in order to ship dangerous goods.

Labeling and Marking Diagram
The following diagram shows how the package must look to ensure it meets IATA and DOT regulations

**NOTE:** Do not write “specimens” or “diagnostic specimens” on the outer box. Diagnostic specimens are subject to specific packaging and training requirements that are not covered in this guidance document. Please contact at (734) 647-1143 if you have any questions regarding classifying your shipment.

![Labeling and Marking Diagram]

Proper Packaging of A Shipment Including Dry Ice

- Place labels on vertical side of box (not top or bottom)
- Ensure shipment will arrive during business hours
- Ensure packaging is constructed for proper venting (unvented dry ice can explode)

**Do Not Forget the Shipment Specific Labels**
Based on What is Being Shipped (e.g. Cat B, Exempt or GMMO)
Printable Labels

Printable Category B Shipment Labels

Print this page and cut out labels to affix to the box (packing tape is recommended). Use wide clear tape to completely cover labels to protect the labels from the weather (rain, snow).
Printable Exempt and Unregulated Shipment Labels

Print this page and cut out labels to affix to the box (packing tape is recommended). Use wide clear tape to completely cover labels to protect the labels from the weather (rain, snow).
Printable GMMOs and GMO Labels

Print this page and cut out labels to affix to the box (packing tape is recommended). Use wide clear tape to completely cover labels to protect the labels from the weather (rain, snow).

Use the following Class 9 shipping label if shipping the package without dry ice.
Printable Ethanol, Formaldehyde, and Formalin (Exempt Quantities) Labels

The labels must be printed in color, and the following information must be written on the appropriate lines.

- Line One: Hazard Class Number
- Line Two: Write name/address Shipper/Consignee (if not on the shipping label)

Print this page and cut out labels to affix to the box (packing tape is recommended). Use wide clear tape to completely cover labels to protect the labels from the weather (rain, snow).