

# Packaging Requirements to Transport Biological Substances & Hazardous Materials

## Manual

Revision Date: 04/18/18

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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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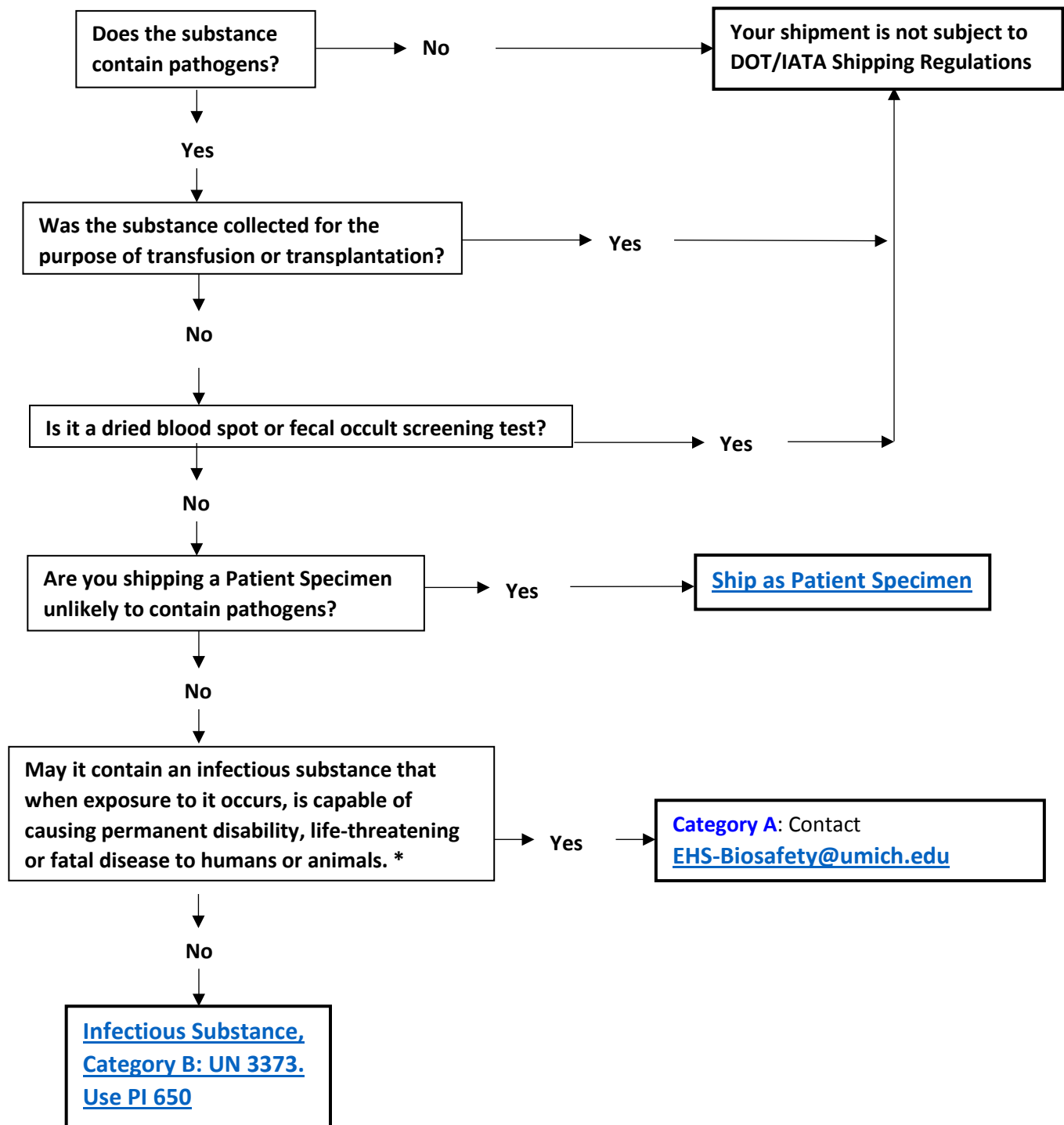
## Minimum Requirements for Securing Biological Substances and Hazardous Materials

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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



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## Category A Infectious Substances

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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

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## Category B Infectious Substances

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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

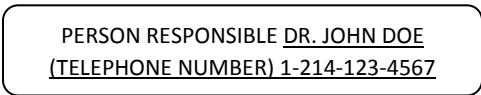

### IATA/DOT Packing Instructions


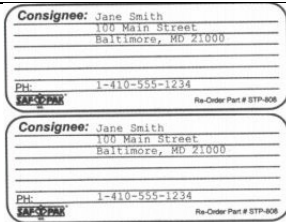


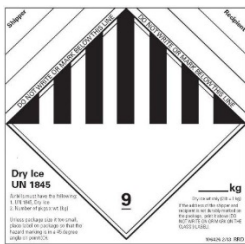
Category B infectious substances and cultures **must** be packaged using the IATA/DOT Requirements for Packing Instructions (PI) 650.

**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:

LABEL	NAME
	Shipper/Responsible Party Label <b>NOTE:</b> This label <b>must</b> be on the outside of the package or on the air waybill
	UN3373 label Category B infectious substances and UN3373 label <b>NOTE:</b> The outer package <b>must</b> bear two labels or one 1 combined label

LABEL	NAME
	<p>Orientation label</p> <p><b>NOTE:</b> Use this label for shipments that include more than 50 mL of liquid</p> <p><b>NOTE:</b> An orientation labels <b>must</b> be placed on two opposite sides of the package The arrows <b>must</b> be oriented with the primary receptacles.</p>
	<p>Shipper and Receiver Address label</p>
 	<p>Class 9 Miscellaneous Dangerous Good label</p> <p>Dry Ice UN 1845 label</p> <p><b>NOTE:</b> All packages containing dry ice <b>must</b> have these two markings in one of the following formats:</p> <ul style="list-style-type: none"> <li>Separate class and UN label</li> <li>A label containing both the class and UN number</li> </ul> <p>The class label and the UN number handwritten on the package</p>
<p>Or</p>	
	

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## Exempt and Unregulated Specimens

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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 known 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, secretions, 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***


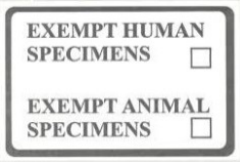

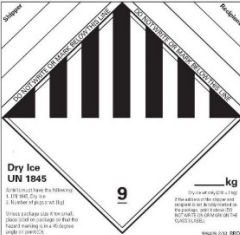
Use the following criteria to determine if a specimen is exempt from IATA and DOT regulations:

- 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:

LABEL	NAME
	Shipper and Receiver Address label
	Exempt Human Specimens and Exempt Animal Specimens combined label
 <p>Or</p> 	<p>Class 9 Miscellaneous Dangerous Good label Dry Ice UN 1845 label</p> <p><b>NOTE:</b> All packages containing dry ice <b>must</b> 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</p>

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## Genetically Modified Micro-Organisms and Genetically Modified Organisms

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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

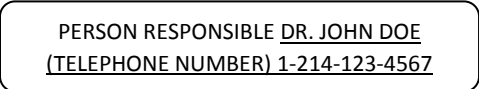


### **IATA/DOT Packing Instructions**

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:

LABEL	NAME
	Shipper/Responsible Party Label  <b>NOTE:</b> This label <b>must</b> be on the outside of the package or on the air waybill
 	UN3245 label Class 9 Miscellaneous Dangerous Goods label  <b>NOTE:</b> For packages being shipped internationally, the outer package containing GMMOs or GMOs <b>must</b> bear both labels

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**LABEL**

Consignee: Jane Smith  
100 Main Street  
Baltimore, MD 21000  
Ph: 1-410-555-1234  
Re-Order Part # STP-808

Consignee: Jane Smith  
100 Main Street  
Baltimore, MD 21000  
Ph: 1-410-555-1234  
Re-Order Part # STP-808

**NAME**

Shipper and Receiver Address label



Orientation label

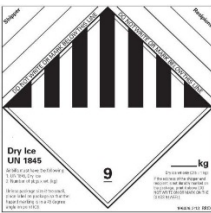
**NOTE:** Use this label for shipments that include more than 50 mL of liquid

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

Class 9 Miscellaneous Dangerous Good label  
Dry Ice UN 1845 label

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

Or



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

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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:

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

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

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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:

PACKAGING	MAXIMUM VOLUME (AMOUNT)	EXAMPLES
A leak proof primary receptacle	1L/primary receptacle	<ul style="list-style-type: none"><li>• Cryovial</li><li>• Test tube</li><li>• Eppendorf tube</li><li>• Petri plate (inside a ziplock bag)</li></ul>
A leak proof secondary packaging	Liquid: 4L or 4Kg/package Solid: 4Kg/package	<ul style="list-style-type: none"><li>• Sealed plastic ziplock bag</li><li>• Sealed plastic containers</li><li>• Conical tubes</li></ul>
Outer packaging		<ul style="list-style-type: none"><li>• Insulated cooler</li></ul>

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.

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## **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".

## 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).



**Shipper** **Recipient**

DO NOT WRITE OR MARK BELOW THIS LINE

DO NOT WRITE OR MARK BELOW THIS LINE

**Dry Ice**  
**UN 1845**

\_\_\_ kg

**9**

Airbills must have the following:  
1. UN 1845, Dry Ice  
2. Number of pkgs x wt. [kg]

Unless package size it too small,  
place label on package so that the  
hazard marking is in a 45 degree  
angle on point (◊).

Dry ice wt only (2lb = 1 kg)  
If the address of the shipper and  
recipient is not durably marked on  
the package, print it above (DO  
NOT WRITE ON OR MARK ON THE  
CLASS 9 LABEL).

106426 2/13 RRD

## 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).

<b>EXEMPT HUMAN SPECIMENS</b>	<input type="checkbox"/>
<b>EXEMPT ANIMAL SPECIMENS</b>	<input type="checkbox"/>

<i>Shipper</i>	<i>DO NOT WRITE OR MARK BELOW THIS LINE</i>	<i>DO NOT WRITE OR MARK BELOW THIS LINE</i>	<i>Recipient</i>
<b>Dry Ice</b> <b>UN 1845</b>			
<b>9</b>			
Airbills must have the following: 1. UN 1845, Dry Ice 2. Number of pkgs x wt. [kg]		_____ <b>kg</b> Dry Ice wt only (2lb = 1 kg) If the address of the shipper and recipient is not durably marked on the package, print it above (DO NOT WRITE ON OR MARK ON THE CLASS 9 LABEL).	
Unless package size is too small, place label on package so that the hazard marking is in a 45 degree angle on point (◊).		106426 2/13 RRD	

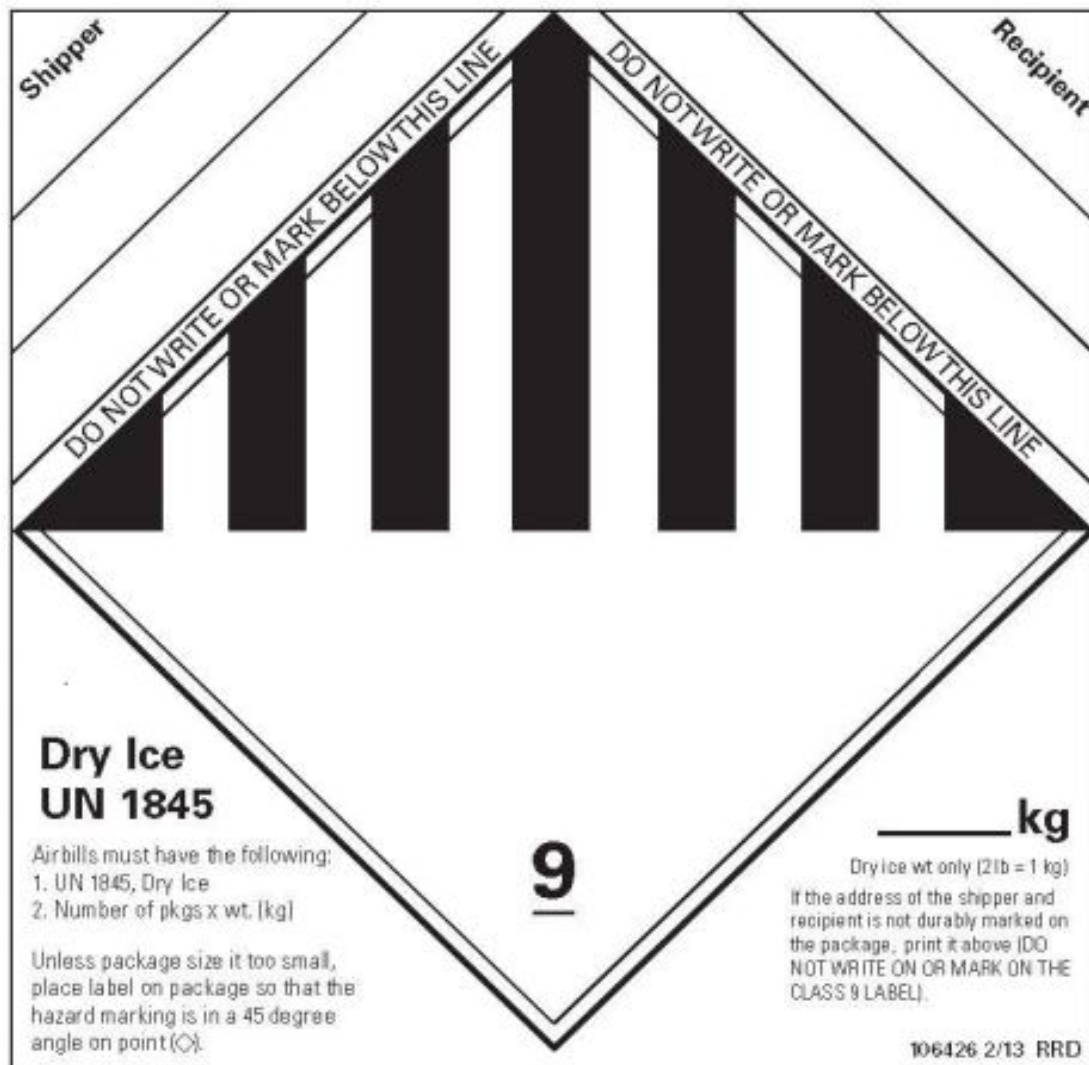


## Printable GMMOs and GMO Labels

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.



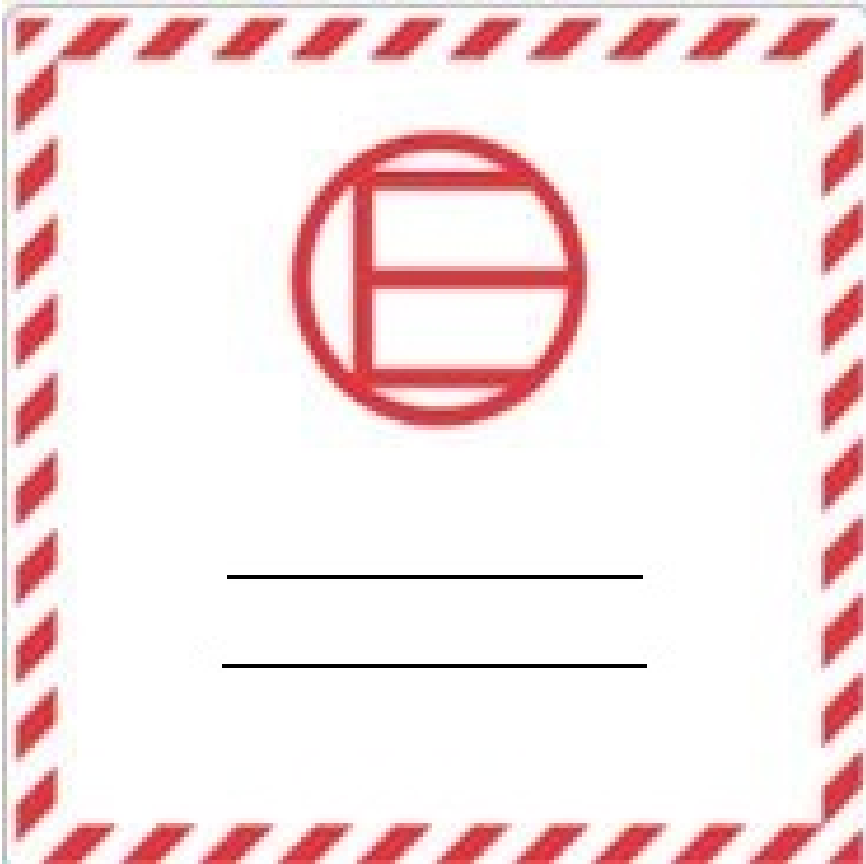
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### Printable Ethanol, Formaldehyde, and Formalin (Exempt Quantities) Labels

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).



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### Revision History

REVISION #	DATE	REVISION #	DATE	REVISION #	DATE	REVISION #	DATE
3	11/8/17						
4	4/18/18						