

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Introduction

Welcome to the **Shipping Biological Substances, Category B (OHS_BIO201)** Training Course. This course is **REQUIRED** for anyone that will be shipping samples considered Biological Substances, Category B Genetically Modified Organisms (GMOs), Exempt Human or Animals Specimens.

UAB **REQUIRES** additional shipping training for anyone that will be packing:

- Shipping with Dry Ice (BIO200)
- Shipping Infectious Substances, Category A (BIO202)



Failure to properly pack and ship materials is a **VIOLATION** of the law and is punishable with fines and/or imprisonment.

Objectives

At the conclusion, participants should be able to:

1. Identify and properly classify Biological Substances, Category B, Genetically Modified Organisms (GMO), or Exempt Human or Animal Specimens intended for shipment.
2. Correctly pack samples with appropriate primary and secondary containment.
3. Use correct Marks and Labels on packaging.
4. Properly complete the appropriate shipping documents.
5. Follow necessary safety guidelines to avoid any accidents or injuries.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Overview

When shipping Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens, you are bound by regulations that come from several International and National agencies. These regulatory bodies ensure that infectious substances or materials are transported as safely as possible, most notably, by air.

Regarding the shipping and receiving of Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens, the University of Alabama at Birmingham follows both the:

- International Air Transportation Association Dangerous Goods Regulations (IATA-DGR)
- United States Department of Transportation Hazardous Materials Title 49 Code of Federal Regulations Parts 171-180

Shipper Responsibilities

When shipping packages containing Genetically Modified Organisms (GMOs), Exempt Human or Animal Specimens, or Biological Substances, Category B from UAB, you have the responsibility to properly:

- Classify the substance or material
- Identify the substance or material
- Select the appropriate packaging system
- Pack the substance or material
- Mark and Label the package correctly

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Classification

Classification is necessary in order to follow both International and National regulations. Classification of an item to be shipped is used to identify the **ACTUAL** hazard and **NOT** the substance itself.

Biological Substances, Category B

Samples that **DO NOT MEET** the criteria for Infectious Substances, Category A may qualify for classification as Biological Substances, Category B. This means that your specimen is not known or reasonably expected to contain pathogens. Use the [Classification Flowchart](#) on the website to assist you.

Exempt Human or Animal Specimens

If your sample is **NOT** Category A or B, it may fall under the definition of an Exempt Human or Animal Specimen. These Exempt Human or Animal Specimens are those which have minimal likelihood of pathogens being present.

Do not assume your sample is an Exempt Human or Animal Specimen. Professional judgement is required to determine if a substance is exempt. Any professional judgment made should be based on known medical history, symptoms, and the likelihood of pathogens present in the local population from which the sample was obtained. If professional judgement is not available the specimen **MUST NOT** be shipped as Exempt Human or Animal Specimen. If you have questions, please call the Occupational Health and Safety office to get further clarification.

Examples of Exempt Human or Animal Specimens often include:

- Blood or urine to monitor:
 - Cholesterol levels
 - Blood glucose
 - Hormone levels
- Biopsies to detect cancer and test to monitor organ function in humans and animal with non-infectious diseases.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Genetically Modified Organisms (GMO)

Genetically Modified Organisms that do not meet the definition of Category A or B Infectious Substances are assigned to Class 9 (Miscellaneous Hazard).

Identification

UN and PSN

United Nation (UN) Number

These numbers are taken from the List of Dangerous Goods, and are used to identify a substance or group of substances. This UN Number always precedes the Proper Shipping Name (PSN):

- UN 3373 Biological Substances, Category B
- UN 3245 Genetically Modified Micro-Organisms or Genetically Modified Organisms (GMOs)
- Exempt Human or Animal Specimens do **NOT** have a UN Number

Proper Shipping Name (PSN)

The Proper Shipping Name (PSN), is assigned by IATA, ICAO, 49 CFR, and is the name used on shipping documents to describe substances.



The words **DIAGNOSTIC SPECIMEN** and **CLINICAL SPECIMEN** are **NO LONGER ALLOWED** as Proper Shipping Names (PSN).

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Packaging System

Selecting the Proper Packaging

Biological Substances, Category B

Packaging components for Biological Substances, Category B must pass testing requirements as a system, so mixing and matching packaging components from different manufacturer's is **NOT ALLOWED**. For example, you cannot ship Biological Substances, Category B in an EXAKT-PAK™ secondary container and in a SAF-T-PAK™ outer container (fiberboard box). All containers have to be tested and certified together.



Disposable components of a packaging system **MUST** be replaced by components from the same vendor that have been tested and certified for **THAT** packaging system. **SUBSTITUTING ALTERNATIVE PRODUCTS IS A VIOLATION OF THE LAW!**

Outside Packaging

The recommended outside packaging must be **STURDY** and **RIGID**. The outside packaging is typically corrugated fiberboard box and should be the appropriate size for the intended content. The box also serves as a surface for displaying clear marks, labels, and other important information.

Never use boxes except those that conform to approved standards. Always look for the UN mark. It indicates that the box has been tested and meets standards. If you have questions about which boxes are approved, please call OH&S at (205) 934-2487.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Inside Packaging

To be precise:

- Biological Substances, Category B are shipped using Packing Instructions 650 (or PI 650).
- Exempt Human Specimens do not have designated Packaging Instructions so they should be triple-packed to prevent any release or leak of substance. Non-infectious Genetically Modified Organisms (GMOs) are packed using PI 959.
- Any substances identified as UN 3373 must be **TRIPLE PACKAGED** in approved boxes only.
- Shipping liquids are of special concern when traveling by air due to air pressure changes that may occur during a flight. If the shipment is liquid, then the primary or secondary container must be able to withstand air pressure changes without leakage. Documentation of testing is available from the manufacturer.



All packaging components for Biological Substances, Category B must be assembled per the manufacturer's closing instructions specific to the packaging system purchased.

Marking and Labeling

General Information

Marks and Labels are used to provide information about the contents of the package, the nature of the hazard, and any special handling requirements. Any Marks and Labels should be durable, placed so that they are completely visible, not obscured by any other Labels or Markings, and placed all on the same face of the package, if possible.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Biological Substances, Category B

Biological Substances, Category B shipments require the labels described below.

- A Biological Substances, Category B black & white Diamond-on-Point label
- Proper Shipping Name and UN Number (which is “UN3373 Biological Substances, Category B”)
- Complete name **AND** address of the Shipper **AND** Consignee (Receiver)
- Name and telephone number of a responsible person. This must be a reliable and responsible person that will answer the phone (**NO** voicemail and **NO** answering machines). They should be able to answer any questions about the content, shipper, recipient details, and/or permit inquiries.



Exempt Human or Animal Specimens

Packages containing Exempt Human or Animal Specimens must be:

- Packed to prevent leakage
- Include the complete name **AND** address of the Shipper **AND** Consignee
- Marked with the Proper Shipping Name either
 - Exempt Human Specimen
 - Exempt Animal Specimen
- Do **NOT** use a UN 3373 Diamond-on-Point Label
- Remember to remove or completely cover any irrelevant Marks or Labels

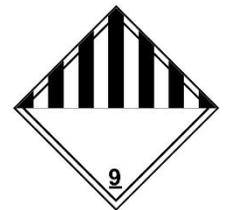


Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Genetically Modified Organisms (GMO)

Packages containing Genetically Modified Organisms (GMO) (including Genetically Modified Micro-organisms) should include:

- The complete name **AND** address of the Shipper **AND** Consignee (Receiver)
- The name and telephone number of a responsible person
- The UN 3245 Genetically Modified Micro-Organisms mark
- The Class 9 Miscellaneous Hazard black-white label
- Remove or completely cover any irrelevant Marks or Labels



If you have any questions about the appropriate required Markings and Labels, contact OH&S at 205-934-2487.

Documentation

If the items you are shipping **DO NOT** require a Shipper's Declaration [Non-dangerous goods, Biological Substance, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens] then the following information must be included on the waybill on the "Nature and Quantity of Good" section:

- UN Number
- Proper Shipping Name
- The Class or Division Number: 9
- The number of packages
- The Net Weight of the Dry Ice in each package, if appropriate

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Additional documentation (i.e., permits or certificates) may be required when shipping Biological Substances, Category B. When shipping internationally, the shipper is responsible for obtaining an export permit. The receiver is responsible for obtaining all permits, including USDA permits for interstate travel, or those required for any countries through which the package will travel.

| Permits or Certificates Required | Shipper's Responsibility | Receiver's Responsibility |
|------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| USDA permits required for certain human or animal pathogens. Per regulations by the USDA, or the CDC | When shipping internationally, the shipper is responsible for obtaining the import and/or export permit. | The receiver is responsible for obtaining all permits necessary for any countries through which the package will travel. |

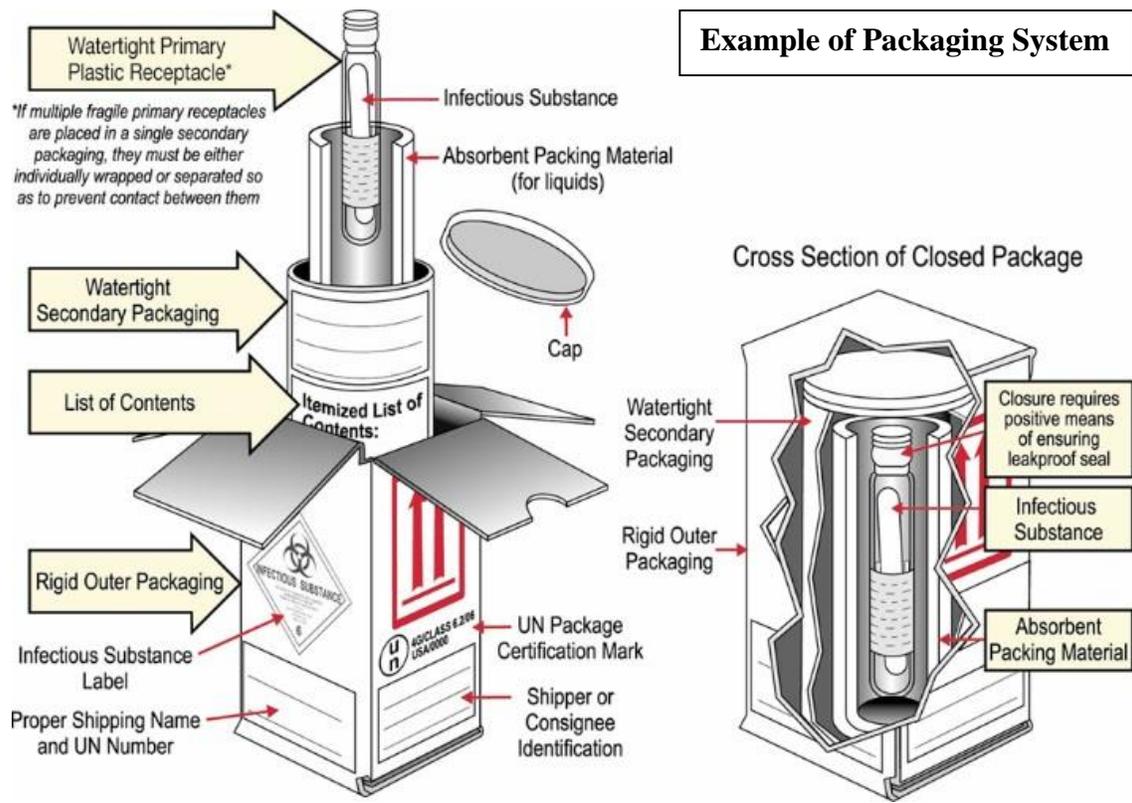
Example

The picture on the next page demonstrates how to properly pack a Biological Substances, Category B package. If the manufacturer's closure instructions are not printed directly on the box, the shipper is required to maintain a copy of the instructions for 90 days from the time the shipment was offered for transport.

You should pack using the ICAO/IATA Packing Instructions:

- 954 for Dry Ice shipments
- 650 for Biological Substance, Category B

Shipping Biological Substances, Category B (OHS_BIO201) Course Material



- A. The primary container is the screw-capped tube. Multiple fragile primary containers must be wrapped individually. It is also recommended that the closures of primary containers be secured by positive means (e.g., lids taped closed).
- B. The secondary container must be an airtight, leak-proof container. Specialized screw-capped plastic or metal jars, or sealable plastic bags, are commonly used as necessary containers in vendor-supplied systems.
- C. This secondary container must also have enough absorbent material to absorb the entire contents, should the primary container fail. For infectious substances, the package must be designed to secure the secondary packaging in the original orientation.
- D. An itemized list of contents goes between the secondary container and the outer packaging.
- E. The third container must be crush-proof to protect the items. If the contents are classified as Biological Substances, Category B, the packaging system used must also pass designated testing specifications.
- F. If using a Styrofoam box, it must fit securely inside the corrugated fiberboard box .
- G. Marks and Labels are placed on the outer container.

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Operator (or Carrier) Responsibilities

Not all couriers/carriers will transport all Biological Substances, Category B, **AND** not all countries or states in the U.S. accept Biological Substances, Category B.

Where there are variations (restrictions) by state/country or courier/carrier, they may be more restrictive than the IATA DGR or ICAO TI, but never less restrictive. **An example of this would be Federal Express's forms.** When shipping FedEx, **ONLY** typed or computer-generated forms are allowed. Packages with handwritten forms **will not be accepted.**

Commercial Courier

The airline industry is very strict about transporting biological materials. You **CANNOT** carry these materials/samples onto a passenger plane no matter how it is packaged. You **MUST** use commercial couriers such as UPS, USPS, FedEx, or DHL. There are quantity limitations, depending on the samples being shipped, and on the courier's method of transport. For more information, please check with OH&S and/or your courier.

Security



SECURITY of the package is the shipper's responsibility until it is handed off to the authorized carrier!

After preparing the package for shipment, the package must remain under the direct control of trained personnel until it is handed over to the carrier. This reduces the chances of tampering, theft, destruction, or invalidating the shipper's signature that signifies the package has been prepared in accordance with 49 CFR/IATA regulations.



If you suspect a package has been tampered with, notify UAB OH&S **IMMEDIATELY!**

Shipping Biological Substances, Category B (OHS_BIO201) Course Material

Before handing the package over to the carrier for shipment, it is the shipper's responsibility to ensure that all Federal and International regulations are met. International shipments may require additional permits. Use the checklist to fulfill courier/carrier variations.

Receiver (or Consignee) Responsibilities

If you are expecting to receive packages containing Biological Substances, Category B at UAB, you have the responsibility to:

- Inspect the documents
- Inspect the package
- Get an import permit if necessary
- Report any damages to the shipper and UAB Biosafety
- Notify the sender that the package has arrived
- Keep all shipping documents for a minimum of three years

Conclusion

This concludes the **Shipping Biological Substances, Category B (OHS_BIO201)** training course. You should now take the assessment. 85% or higher is considered passing. You have three chances to successfully complete the assessment. Failing all three attempts means that you fail the course and must start over.

Want to Learn More?

OH&S has many training courses available to all UAB active employees and students. This includes topics such as in depth radiation training, biosafety, bloodborne pathogens, chemical safety, Controlled Substances, building life safety, hazardous and medical waste, universal waste, PPE, Hazard Communication, etc.

We have a [decision tree](#) to assist you in choosing the right course to match the knowledge/skills you may need at work every day as well.

If you have any questions or comments, please feel free to contact OH&S at 205-934-2487.