GUIDELINES FOR SHIPPING NONPATHOGENIC BIOLOGICAL CULTURES AND NON-INFECTIOUS BIOLOGICAL MATERIALS

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GENERAL INFORMATION

This document provides general information on shipping non-pathogenic biological materials. If you need more specific information please contact Ryan Davis at x7-9375 for further assistance. Note: Biological materials, for which a license or a state or federal permit is required, also require registration with Ryan Davis.
Generally non-pathogenic biological cultures are not specifically regulated. Good practice and concerns for bioterrorism are the basis for asking KGI workers offering biological materials and cultures for shipment to take responsibility for properly

- identifying
- classifying
- packaging
- marking
- labeling, and documenting

The minimum recommended packing procedure, identified below, shall be followed for shipping of all non-pathogenic materials from KGI.

REGULATIONS

All major shippers use the International Air Transport Association (IATA) regulation, also referred to as the Dangerous Goods Regulation (DGR) as their standard. Complying with IATA will ensure you meet the provisions of other US regulations. The regulations and documents identified below apply to the packaging and shipment of regulated biological materials. In most cases, failure to adhere to these regulations is a criminal offense.

- U.S. Department of Transportation, 49 CFR Parts 171-180 and amendments
- U.S. Public Health Service, 42 CFR Part 72, Interstate Shipment of Etiologic Agents
- U.S. Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Blood borne Pathogens
- International Air Transport Association (IATA), Dangerous Goods Regulations
- U.S. Postal Service, 39 CFR Part 111, Mailability of Etiologic Agents, Mailability of Sharps and Other Medical Devices, and Publication 52, Acceptance of Hazardous, Restricted or Perishable Matter
- International Civil Aviation Organization, Technical Instructions for the Safe Transport of Dangerous Goods by Air
- United Nations, Recommendations of the Committee of Experts on the Transportation of Dangerous Goods

It is your responsibility as the shipper to determine whether your biological materials are subject to the requirements of any of these regulations. Most non-pathogenic biological materials are not regulated but if you have any doubt about the material you want to ship, review the definitions below and contact Barb Erwin if you need further assistance.

REGULATION DEFINITIONS

Infectious Substances or Etiologic Agents:

DOT definition: A viable microorganism or its toxin, that causes or may cause disease in humans or animals.

IATA definition: Substances known to contain, or reasonably expected to contain, pathogens.

Pathogens are microorganisms (including bacteria, viruses, rickettsia, parasites, fungi) or recombinant microorganisms (hybrid or mutant) that are known or reasonably expected to cause disease in humans, plants or animals.

Biological Materials:

Biological materials include infectious substances (etiologic agents), diagnostic (clinical) specimens, and other biological products (see Biological Product below).

Diagnostic Specimen:

Any human or animal material including excreta, secreta, blood, blood components, tissue, and tissue fluids being shipped for the purposes of diagnosis.

Please note that diagnostic specimens that are "known or reasonably expected" to contain pathogens must be handled as infectious substances.

Biological Product:
A product prepared in accordance with regulations that govern vaccines, licensed biological products, diagnostic products, etc

Note: Non-pathogenic low-hazard biological products such as Escherichia coli K-12 do not fall into any of the categories listed above in definitions.

Packages must be clearly labeled as to the contents and constructed of materials to protect the specimen and prevent leakage.

Additionally, the OSHA blood borne pathogens standard requires all packages containing blood products be labeled with the biohazard label. For instructions on shipping cultures of pathogenic organisms or infectious materials please see the fact sheet on "Shipping Infectious Materials."

Guidelines for the Packaging for Shipment of Non-Infectious Biological Materials and Non-Pathogenic Cultures

Testing Requirements
There are no testing requirements for containers used to ship non-pathogenic cultures or non-infectious biological materials.

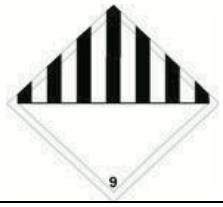
Recommended Packaging for Non-Pathogenic Biological Materials

Primary container (innermost container):
1. Use a vial, tube or plate made of glass, metal, plastic or other medium suitable for transportation of the material being shipped.
2. Clearly identify the contents and avoid abbreviations (e.g. write out E. Coli K-12 - DH1 rather than just DH1).
3. Reinforce screw caps and plates with an adhesive tape, use a metal crimp seal or skirted stopper for metal and glass.

Secondary container:
1. Use a watertight/leak proof container and reinforce with an adhesive tape as necessary to contain the contents (e.g. zip-lock type bag).
2. Affix a label with a complete list of the contents including the scientific name and the amount in ml for liquids.
3. Surround each primary container with sufficient absorbent packing material to completely absorb the contents should the primary container break

Shipping container:
1. Use a container made of sufficient strength to protect the specimen.
2. Affix a proper label to identify the contents.

3. Affix an accurate address label with the complete address and phone number for both the shipper and the recipient.
4. Affix the "double up arrows" sticker if orientation is important.
5. If dry ice or liquid nitrogen is used in the packaging, these materials must be declared, and packages must be properly labeled with an ORM class 9 label and a Shipper's Declaration for Dangerous Goods must be completed. Contact Barb Erwin x7-0160 if you need assistance in completing this form. **Note: Dry ice should never be placed in a sealed container.**



UNIVERSAL PRECAUTIONS

Universal precautions are designed to protect the handler from exposure to blood borne pathogens and at a minimum it is to include:

1. Wearing of protective latex or vinyl gloves or gloves of other appropriate materials when handling or processing specimens
2. Washing your hands after completing your work and removing gloves
3. Wearing a lab coat, apron or other suitable outer garment to prevent contamination of clothing
4. Wearing a face shield or other face protection if there is the possibility of splatter
5. Prohibiting the application of lipstick or other makeup in areas where blood or pathogenic organisms are handled or processed
6. Prohibiting the consumption of food or beverages in areas where blood or pathogenic organisms are handled or processed

Note: When handling human blood always use "Universal Precautions." If the blood is a diagnostic specimen it can be shipped without the dangerous goods paperwork. However, if the human blood is known to be infected with an infectious substance, it must be packaged and shipped as such and requires the dangerous goods paperwork (see fact sheet on shipping infectious materials for more detail).

RESOURCES FOR PACKING SUPPLIES

- CargoPak: http://www.cargopak.com/
- Rose Container Company: http://www.rosecontainer.com/
- ICC, The Compliance Center: http://www.thecompliancecenter.com/products.htm
- Saf-T-Pak, Inc.: http://www.saftpak.com
- Cold Chain Technologies: http://www.coldchaintech.com/containers/biocool_diagnostics.html
- In Mark Inc.: www.inmarkinc.comLab Safety Supply