Shipping Infectious Substances, Biological Substances and Related Hazards
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Disclaimer
The information contained herein is abridged from legislation, regulations and administrative rulings from various government agencies, trade associations and other institutions and should not be construed as legal advice or opinion. While every effort has been made to ensure the accuracy of the information contained herein, legislation, regulations and practices are constantly being reviewed and changed. HighQ LLC shall not be responsible for any loss or damage whatsoever caused by any errors, omissions, misprints or misinterpretations of any of the information in this manual.
The Agencies and Organizations

**DOT (Department of Transportation)**

is the competent authority in the United States for interpretation and enforcement of shipping practices.


**DOT Sub-agencies**

- **PHMSA (Pipeline and Hazardous Materials Safety Administration)** has public responsibilities for safe and secure movement of hazardous materials to industry and consumers by all transportation modes, including the nation’s pipelines.

- **FAA (Federal Aviation Administration)** is the DOT responsible for domestic air travel.

  www.faa.gov

- **FMCSA (Federal Motor Carrier Safety Admin) Road Regulations**

Publication: The Code of Federal Regulations Title 49 (49 CFR)

**ICAO (International Civil Aviation Organization)**

is the United Nations associated organization that develops regulations for the safe transport of dangerous goods by air.

Publication: ICAO Technical Instructions  www.icao.org

**IATA (International Air Transport Association)**

is a trade association made up of airlines and air cargo carriers. IATA annually publishes a book of regulations which interprets and enhances the ICAO Technical Instructions to reflect industry practices.

Publication: Dangerous Goods Regulations  www.iata .org

**CDC (Centers for Disease Control)**

a division of the US Health and Human Services Agency has guidelines for the interstate shipping of infectious substances as well as minimum standards for packaging and labeling diagnostic specimens and biological products. They also include a list of special agents for which specific label and special tracking is required.

Publication: 42 CFR, Part 72  www.cdc.gov

**OSHA (Occupational Safety and Health Administration)**

assures workplace safety and is involved in governing occupational exposure to blood borne pathogens.


The **DOT is our competent authority** in the United States, therefore, they are the agency responsible for enforcement and interpretation of the regulations.
THE W’s of TRAINING

WHO (Applicability Requirements)
49 CFR 171.1(b) Apply to each person who offers a hazardous material for transportation in commerce, causes a hazardous material to be transported in commerce or transports a hazardous material in commerce and performs or is responsible for performing a pre-transportation function….shall be subject to and comply with all provisions of the Federal Hazardous Materials Transportation law, all orders and regulations issued hereunder…

Training
49 CFR 172.700 (subpart H)
   173.1 (subpart A), specific 172.704
IATA 1.5/ ICAO Chapter 1.4  (Instructor Qualifications)

Responsibility
49 CFR 172.702 Employers shall ensure that each hazmat employee is trained.
49 CFR 172.704 (a) Hazmat employee training shall consist of the following:

WHAT
1. General Awareness/Familiarization Training
2. Function Specific Training
3. Safety (emergency response) Training (subpart G)
4. Security Awareness  (subpart I)

WHEN
Training is to take place:

   Within 90 days after employment or job change (Direct supervision until training takes place)
   Every 3 years (DOT) or 2 years (ICAO/IATA)
   To update changes *High Q helps with this.

WOW
Fines

49 CFR 171.1(g) Each person who knowingly violates a requirement of the Federal Hazardous Material Transportation law…is liable for a civil penalty of not more than $77,114 for each vialation…maximum is $179,933 if the violation results in death… and a minimum $463 civil penalty applies to violation relating to training. …..each day is a separate offense.
General Awareness
Classification and Identification

Shipper’s Responsibility

49 CFR 173.22  ICAO/IATA 1.1.2

(a)(1) The person shall class and describe the hazardous material in accordance with parts 172 and 173 of this subchapter and (2) the person shall determine that the packaging or container is an authorized packaging...

Also General Requirements 171.2 (e)(g)

Classification

Hazard Class and divisions 49 CFR 173.2

IATA Section 3, ICAO Part 2

49 CFR definitions, classifications and exemptions for each class start at 173.50 and continue through 173.156

<table>
<thead>
<tr>
<th>Class</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
<td>Explosives</td>
</tr>
<tr>
<td>Class 2</td>
<td>Gases</td>
</tr>
<tr>
<td>Class 3</td>
<td>Flammable Liquids</td>
</tr>
<tr>
<td>Class 4</td>
<td>Flammable Solids/Dangerous when wet /Spontaneously Combustible Material</td>
</tr>
<tr>
<td>Class 5</td>
<td>Oxidizers and Peroxides</td>
</tr>
<tr>
<td>Class 6</td>
<td>Toxic and Infectious Substances</td>
</tr>
<tr>
<td>Class 7</td>
<td>Radioactive Materials</td>
</tr>
<tr>
<td>Class 8</td>
<td>Corrosives</td>
</tr>
<tr>
<td>Class 9</td>
<td>Miscellaneous Hazardous Material</td>
</tr>
</tbody>
</table>
Packing Groups (PG) – These are designated to indicate the degree of danger presented by the material. Packing Groups are not assigned to all classes of hazardous materials. The shipper is always responsible for determining the appropriate Packing Group.

Examples of package marking:

- UN 4G/Y1.7/S/17/USA/+CE000
- UN 4GV/X2.2/S/10/USA/+CE000
- UN 1A2/Z1.5/100/14/USA/+CE000
Question

What is a Pathogen?

Answer

A pathogen or infectious agent is a biological agent that causes disease or illness to its host.

Definitions

1. Category A - Infectious Substance

DOT49 CFR 173.134 (a)(1)

IATA 3.6.2 6.2/ ICAO– Infectious Substance

Infectious Substances means a material known or reasonably expected to contain a pathogen. A pathogen is a micro-organism (including bacteria, viruses, rickettsia, parasites, fungi) or other agent such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals. An infectious substance must be assigned the identification number UN2814, UN2900, UN3291, or UN3373, as appropriate and must be assigned to one of the following categories:

173.134(a)(1)(i)/3.6.2.2.2.1/ 2.6.2.2 Category A: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. A category A infectious substance must be assigned to UN 2814 or UN 2900 as appropriate. Assignment to UN2814 or UN 2900 must be based on the known medical history and symptoms of the source human and animal, endemic local conditions, or professional judgment concerning individual circumstances of the source human or animal.

173.134(a)(3)3.6.2.1.3/ 2.6.2.1(c) Culture means and infectious substance containing a pathogen that is intentially propagated. This definition does not include patient specimens.
Table 2-10/2.8/3.6.D – (The List)

Indicative examples of Infectious Substances included in Category A in any form unless otherwise indicated ICAO/IATA/A.I.R., DOT list

<table>
<thead>
<tr>
<th>UN Number and Proper Shipping Name</th>
<th>Category A Indicative List</th>
<th>Category A Indicative List</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN2814</strong></td>
<td><strong>Cultures Only</strong></td>
<td><strong>Infectious Substances in any form</strong></td>
</tr>
<tr>
<td>Infectious substance, affecting humans (Meaning humans or both humans and animals)</td>
<td>Bacillus anthracis</td>
<td>Mycobacterium tuberculosis</td>
</tr>
<tr>
<td></td>
<td>Brucella abortus</td>
<td>Polio virus</td>
</tr>
<tr>
<td></td>
<td>Brucella melitensis</td>
<td>Rabies virus</td>
</tr>
<tr>
<td></td>
<td>Brucella suis</td>
<td>Rickettsia prowazeki</td>
</tr>
<tr>
<td></td>
<td>Burkholderia mallei-</td>
<td>Rickettsia rickettsii</td>
</tr>
<tr>
<td></td>
<td>Pseudomonas mallei-</td>
<td>Rift valley fever virus</td>
</tr>
<tr>
<td></td>
<td>Glanders</td>
<td>Russian spring-summer</td>
</tr>
<tr>
<td></td>
<td>Burkholderi pseudomallei-</td>
<td>encephalitis virus</td>
</tr>
<tr>
<td></td>
<td>Pseudomonas pseufomallei</td>
<td>Shigella dysenteriae type 1</td>
</tr>
<tr>
<td></td>
<td>Chlamydia psittici -</td>
<td>Tick-borne encephalitis virus</td>
</tr>
<tr>
<td></td>
<td>avain strains</td>
<td>Venezuelan equine</td>
</tr>
<tr>
<td></td>
<td>Clostridiium botulinum</td>
<td>encephalitis virus</td>
</tr>
<tr>
<td></td>
<td>Coccidionides inmites</td>
<td>West Nile virus</td>
</tr>
<tr>
<td></td>
<td>Coxiella burnetii</td>
<td>Yellow fever virus</td>
</tr>
<tr>
<td></td>
<td>Dengue virus</td>
<td>Yersinia pestis</td>
</tr>
<tr>
<td></td>
<td>Eastern equine encephalitis virus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Escherichia coli,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>verotoxigenic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Francisella tularensis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hepatitis B virus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Herpes B virus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Highly pathogenic avian</td>
<td></td>
</tr>
<tr>
<td></td>
<td>influenza virus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Human</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immunodeficiency virus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis virus</td>
<td></td>
</tr>
</tbody>
</table>

GENERAL AWARENESS
Table 2-10/2.8/3.6.D – (The List)

Indicative examples of Infectious Substances included in Category A in any form unless otherwise indicated ICAO/IATA/A.I.R., DOT list

**UN Number and Proper Shipping Name**

**UN2900**  
Infectious substance, affecting humans (Meaning humans or both humans and animals)

**Infectious Substances in any form (Continued)**

- Hanta viruses causing hemorrhagic
- Marburg virus fever with renal syndrome
- Monkeypox virus
- Hantaan virus
- Nipah virus
- Hendra virus
- Omsk hemorrhagic fever virus
- Junin virus
- Sabia virus
- Variola virus

**Category A Indicative List**

**Micro-organism Cultures Only**

- African swine fever virus
- Avian paramyxovirus Type 1 – Velogenic
- Newcastle disease virus
- Classical swine fever virus
- Foot and mouth disease virus
- Goat-pox virus

- Lumpy skin disease virus
- Mycoplasma mycoides – Contagious bovine pleuropneumonia
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep-pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus

If any doubt what the determination of a specimen is it must be considered Category A.
2. Category B - Biological Substance

**DOT/IATA/ 2.6.2**

173.134(ii)/3.6.2.2.2.2/2.6.2.2(b) **Category B**: An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening disease in otherwise healthy humans or animals... (does not meet the criteria for inclusion in Category A). A Category B infectious substance must be described as “Biological Substance, Category B and assigned identification number UN 3373.

173.134(b) /3.6.2.2.3 /2.6.2.3 Exceptions

- .1 /1,(2) Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

- .2 /3) Substances containing micro-organisms, which are non-pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

- .3/ (4) Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

- .4/ (5) Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection are not subject to these Regulations unless they meet the criteria for inclusion in another class.

- .5 /7),(8),(9) Dried blood spots, collected by applying a drop of blood onto absorbent material, or fecal occult blood screening tests and blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Regulations.
3. Patient Specimens or Exempt Human Specimen

DOT 173.134(a)(4) IATA 3.6.2.3.6 /2.6.2.3(f) Patient specimens for which there is a minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is packed in a packaging which will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen” as appropriate.

Note:
In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the:

- blood or urine tests to monitor:
  - cholesterol
  - levels blood
  - glucose levels
  - hormone levels
  - prostate specific antigens (PSA)

- tests required to monitor organ function such as heart, liver or kidney function for human or animals with non-infectious diseases

- therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol

- pregnancy tests

- biopsies to detect cancer

- antibody detection in humans or animals.

Also 173.134(b) 10,11
3.6.2.7 Patient Specimens must be assigned to UN2814, UN2900 or UN3373 as appropriate except if they comply with 3.6.2.2.3 (exceptions on Pg 13).

Domestic Mail Manual 10.17.2
....Typically, exempt human specimens are specimens for which there is a low probability that the sample is infectious, such as specimens for drug or alcohol testing; cholesterol testing; blood glucose level testing; prostate- specific antigens (PSA) testing; testing to monitor heart, kidney, or liver function; pregnancy testing; and testing for diagnosis of noninfectious diseases such as cancer biopsies.
DOT 49CFR 173.134(a)(2)/IATA 3.6.2.3 Biological Products

(2) Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings or animals. A biological product includes a material subject to regulation under 42 U.S.C. 262 or 21 U.S.C. 151-159. Unless otherwise excepted, a biological product known or reasonably expected to contain a pathogen that meets the definition of a Category A or B infectious substance must be assigned the identification number UN2814, UN2900 or UN3373 as appropriate.

(5) Regulated medical waste clinical waste or (bio) medical waste means a waste or reusable material derived from the medical treatment of an animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production and testing of biological products. Regulated Medical Waste or clinical waste or (bio) medical waste containing a Category A infectious substance, must be classed as an infectious substance and assigned to UN2814 or UN2900 as appropriate.

IATA
3.6.2.5 Medical or Clinical Waste

3.6.2.5.1 Medical or clinical wastes containing Category A infectious substances must be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B must be assigned to UN 3291

3.6.2.5.2 Medical or clinical wasted which are reasonably believed to have a low probability of containing infectious substances must be assigned to UN 3291.

3.6.2.5.3 Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class
DOT 49CFR 173.134(a)

(8) *Used Health Care Product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a patient specimen, biological product, or regulated medical waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation.

DOT 49CFR 173.134(b) Exceptions (excerpt)

(10) A Division 6.2 material, other than a Category A infectious substance contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or a biological product, when such materials are transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination. If the human or animal sample or biological product meets the definition of regulated medical waste in paragraph (a) (5) of this section, it must be offered for transportation and transported in conformance with the appropriate requirements for regulated medical waste.

(11) A human or animal sample (including, but not limited to, secretions, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing that is not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability that the sample is infectious.

(ii) Used Health Care Products
Identification

49 CFR Part 172 The Hazardous Materials Table

IATA Section 4

49 CFR 172.101

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Proper shipping names (PSN)</th>
<th>Hazard Class or Division</th>
<th>Identification Numbers</th>
<th>Packing Group (PG)</th>
<th>Label Codes</th>
<th>Special Provisions (§172.102)</th>
<th>8 - Packaging (§173.400)</th>
<th>9 - Quantity Limitations</th>
<th>Vessel Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8A</td>
<td>8B</td>
<td>8C</td>
</tr>
<tr>
<td></td>
<td>Biological substance, category B</td>
<td>6.2</td>
<td>UN3373</td>
<td>A82</td>
<td>134</td>
<td>199</td>
<td>4 L or 4 kg</td>
<td>4 L or 4 kg</td>
<td></td>
</tr>
<tr>
<td>AW</td>
<td>Dry Ice or Carbon dioxide, solid</td>
<td>9</td>
<td>UN1845</td>
<td></td>
<td>217</td>
<td>217</td>
<td>200 kg</td>
<td>200 kg</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>Infectious substances, affecting animals only</td>
<td>6.2</td>
<td>UN2900</td>
<td>6.2</td>
<td>A82</td>
<td>134</td>
<td>50 ml or 50 g</td>
<td>4 L or 4 kg</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>Infectious substances, affecting humans</td>
<td>6.2</td>
<td>UN2814</td>
<td>6.2</td>
<td>A82</td>
<td>134</td>
<td>50 ml or 50 g</td>
<td>4 L or 4 kg</td>
<td></td>
</tr>
</tbody>
</table>
Column 1: Symbols (DOT)

There are 6 symbols that may or may not be present in this column. **They are A, D, G, I, + and W.**

- **A** means these regulations apply for shipment by Air.
- **W** means these regulations apply for shipment by Water.
- **D** means these regulations are intended for Domestic shipment and may be inappropriate for international.
- **G** means the proper shipping name is General and technical names of the hazardous material must be entered in parentheses, in association with the basic description.

Column 2: Hazardous materials descriptions and proper shipping names

Spell **exactly** like the listing.

Proper Shipping names (PSN) and United Nations Identification Numbers (UNID#) used in shipping biomedical hazards.

<table>
<thead>
<tr>
<th>PSN (Column 2)</th>
<th>UNID# (Column 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious substances, affecting humans</td>
<td>UN2814</td>
</tr>
<tr>
<td>Infectious substances, affecting animals only</td>
<td>UN2900</td>
</tr>
<tr>
<td>Carbon Dioxide, solid or Dry Ice</td>
<td>UN1845</td>
</tr>
<tr>
<td>Biological Substance, Category B</td>
<td>UN3373</td>
</tr>
<tr>
<td>Regulated Medical Waste</td>
<td>UN3291</td>
</tr>
</tbody>
</table>
DOT Hazardous Material Table Continued:

Column 3: Hazard Class or Division

Column 4: Identification Number

Column 5: Packaging Group (When applicable)

Column 6: Labels

Column 7: Special Provisions (listed in DOT and IATA after the hazmat table)

Column 8: Packaging Authorizations Section 173

  8A. Exceptions  173.134 (definitions of infectious substances and exceptions)
  8B. Non-Bulk  173.196 (how to package infectious substances)
  8C. Bulk  none

Column 9: Quantity limitations

  9A. Passenger carrying aircraft or passenger carrying rail

  9B. Cargo aircraft only

Column 10: Stowage requirements

  10A. Stowage locations

  10B. Specific hazardous materials stowage requirements
IATA DGR has 14 columns A through N ICAO 13 columns

- Air only
- Packing Instructions (PI)
  - PI 620- Infectious substances, Category A
  - PI 650- Biological Substance, Category B
  - PI 954- Dry Ice

**Special Provisions**

**A47** Genetically modified micro-organisms and genetically modified organisms packed and marked in accordance with Packing Instruction 959 are not subject to any other requirements of these Regulations.

If GMMO or GMO meet the definition in 3.6 of a toxic substance or an infectious substance and the criteria for inclusion in Division 6.1 or 6.2, the requirements in these Regulations for transporting toxic substances or infectious substances apply.

**A81** The quantity limit shown in Columns J and L do not apply to body parts, organs or whole bodies. *Transport in accordance with this provision must be noted on the Shippers Declaration for Dangerous Goods (A82 in DOT 49 CFR) Transport in accordance with this Special Provision must be noted on the Air Waybill.

**A117** Wastes transported under UN 3291 are wastes derived from the medical treatment of humans or animals or from bio-research, where there is a relatively low probability that infectious substances are present. Waste infectious substances, which can be specified, must be assigned to UN 2814 or UN2900. Decontaminated wastes, which previously contained infectious substances, may be considered as not subject to these Regulations unless the criteria of another Class or Division are met.

**A140** Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assigned to UN 2814 or UN 2900, the words “suspected Category A infectious substance” must be shown, in parentheses, following the proper shipping on the Shipper’s Declaration for Dangerous Goods, but not on the outer packagings.

DOT 49CFR 172.203(k).... A material classed as Division 6.2 and assigned identification number UN 2814 or 2900 that is suspected to contain an unknown Category A infectious substance must have the words suspected Category A infectious substance” entered in parentheses in place of the technical name as part of the proper shipping description...a technical name should NOT be marked on the outer package of a Division 6.2 material.
Function Specific
Package Criteria - Infectious Substances (Category A)

49 CFR 173.196 Packaging and component requirements for infectious substances

ICAO/IATA PI 620 Packaging and component requirements for infectious substances (air shipments)

- Each package must contain a primary and secondary container
  - Both containers must be watertight.
  - One container must pass a 95 kPa (13.8 psi) pressure test. (and withstand temperatures in the range of -40°C to +55°C
  - In the case of multiple primaries, all receptacles must be individually cushioned.
  - Absorbent is required between the primary and secondary containers and must be sufficient to absorb all liquid contents.

- A rigid outer box with a minimum dimension of 100mm (3.9 inches)
- Assembled packages must be capable of passing the tests in 178.609 or IATA 6.5

Additional requirements

- Primary receptacles in ambient packages must be positively sealed such as a heat seal, skirted stopper, tape, etc.
- In frozen packages the dry ice must be outside the secondary container which must remain secure after the ice dissipates. The outer package must also permit the release of the carbon dioxide gas.
- Inner packagings containing infectious substances must not be consolidated with inner packagings containing unrelated types of goods.
- An itemized list of contents must be enclosed between the secondary and outer packaging and state “Suspected Category A Infectious Substance” following the proper shipping name if the substance is unknown and suspected to meet the criteria for Category A.

Quantity limits

DOT 50 ml or 50 g passenger air, 4 L or 4 kg Cargo Only

IATA/ICAO 50 ml or 50 g passenger, 4 L or 4 kg Cargo only
Category A con’t

Other dangerous goods must not be packed in the same packaging as the Division 6.2 Infectious Substances A unless they are necessary to maintain the viability, stability, prevent degradation or neutralizing of the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods in Classes 3 (flammable), 8 (corrosive) or 9 (misc. hazardous material) may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.

Package Tests-Category A

49 CFR 178.609  Details the testing that Class 6.2 packaging must pass.
IATA Sec. 6.5  Details the testing that Class 6.2 packaging must pass.

Drop Test  - 30 feet (9 meters)

- 5 drops in different orientations after conditioning at -18 C for 24 hours.
- 5 drops in different orientations after conditioning in water spray for 1 hour

Penetration Test  - 15 lb steel rod dropped on to the package from 3 feet on the top and side.

Other tests:

  Vibration Test  - vibrating platform that simulates truck bed vibration for 1 hour. (DOT only)

  Stack Test  - packages 10 ft high for 24 hours Variation Packaging rules (U marking)
Certification Marking-Category A

49 CFR 178.503(f) IATA 6.04

Markings on packages for Infectious Substances

UN 4G Class 6.2/17/USA/+CE000

UN 4GU Class 6.2/17/USA/+CE000
(U denotes variation marking which permits different types of primaries.)

Marking consists of:

• UN - The United Nations packaging symbol 4G
• The type of packaging
• Class 6.2 - Hazard class 10
• Year of manufacture
• USA - State (country) authorizing the mark
• XXX - Manufacturer and/or test lab identification
  (+CE is the best but others are acceptable)

Test Reports

49 CFR 178.601(l) IATA Sec. 6.3.7

Following each test a report must be prepared and made available to the users of the packagings and the DOT if requested. The test report must include the following information:

• Name and address of test facility and applicant
• Unique test report identification
• Date of test report
• Manufacturer of the packaging
• Description of the packaging (type, dimensions, etc.)
• Maximum capacity
• Closure Instructions 178.2(c)
• Test descriptions and results
• Signed with name and title of signatory
Labeling – Category A

49 CFR 172.407 Label Specifications Infectious

Label 49 CFR 172.432/IATA Sec. 7

The Infectious substance label is to be affixed to a single surface (square-on-point) near the PSN and UN ID number.

Size 3.9”x3.9” or 100mm x 100mm

IATA 7.2.2.3.1/7.3.15 ICAO 3.5.1.1
(size may be reduced no smaller than 50mm x 50mm for small packages)
Package Marking –Category A

The shipper is responsible that each package containing hazardous materials has markings in accordance with the regulations, and that the packagings are of sufficient size to accommodate all marking and labeling. Also take into consideration that shipping documents are to be attached and cannot cover the markings or labels in any manner.

49 CFR 172.301

IATA Sec. 7.1.5.1

(a) Proper Shipping Name and UN Identification Number. (S.P. A140)

(b) Shippers and Consignees full name and address.

(c) The Net Quantity of dangerous goods contained in each package must be shown adjacent to the UN number and Proper Shipping Name when there is more than 1 package in the consignment.

(d) For UN1845 – Carbon dioxide solid (dry ice) the NET QUANTITY of dangerous goods contained in each package must be shown.

(f) The Name and Telephone number of a responsible person for Division 6.2 Infectious substance shipments.

(g) For packages containing UN3373 “BIOLOGICAL SUBSTANCE, CATEGORY B" the diamond shaped marking from PI 650

* Packages containing biological substances are not required to have the net quantity marked on the package. However when dry ice is used the net quantity of dry ice must be shown.

49 CFR 172.312

IATA 7.2.4.4

Package Orientation Arrows are required for packages containing liquid hazardous materials. A minimum of two (2) arrows on opposing vertical sides. Red or Black on contrasting background. Size 75mm x 105mm

172.312(c)(6) Excluded from this rule: Infectious substances with primaries of 50 ml (1.7 Fl.oz.) or less do not require the Orientation Arrows marking. (c)(3) Also for 120ml (4 Fl. Oz) or less of flammable liquids. A.I.R. 5.3.6.2 ..not smaller than half the size..
Shipping Papers and Documentation Category A

49 CFR 172.200

IATA Section 8

Properly filling out the shipping papers is one of the most important aspects of hazardous packaging because it is the most inspected and scrutinized part of the process. It is the most detailed description of the materials enclosed within the package, as well as handling and contact information. It is a signed legal document that creates a contract between the shipper and carrier.

IATA 8.1

Shippers Declaration for Dangerous Goods

| Hatchings must be red |

<table>
<thead>
<tr>
<th>Shipper</th>
<th>Air Waybill No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Page of Pages</td>
</tr>
<tr>
<td></td>
<td>Shipper's Reference No. (optional)</td>
</tr>
</tbody>
</table>

**TRANSPORT DETAILS**

This shipment is within the limitations prescribed for: (delete non-applicable)

<table>
<thead>
<tr>
<th>Airport of Departure:</th>
</tr>
</thead>
</table>

**SHIPS DECLARATION FOR DANGEROUS GOODS**

**Air Waybill No.**

**Page of Pages**

**Shipper’s Reference No. (optional)**

**AIRPORT OF DESTINATION:**

**NATURE AND QUANTITY OF DANGEROUS GOODS**

<table>
<thead>
<tr>
<th>Dangerous Goods Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN/ID No.</td>
</tr>
</tbody>
</table>

**ADDITIONAL HANDLING INFORMATION:**

"Prior arrangements as required by IATA Dangerous Goods Regulations 1.3.3.1 have been made."

Prepared according to ICAO/IATA.

| 24hr. Emergency Contact No. |

**I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked, labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national government regulations.**

<table>
<thead>
<tr>
<th>Name/Title of Signatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place and Date</td>
</tr>
</tbody>
</table>

**SIGNATURE**

(see WARNING above)

**FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT: THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.**
1. Shipper name and address
2. Consignee name and address
   - Infectious Substance requires phone number
   - 49 CFR 172.604(c)
     - 24 hour phone number-monitored entire time substance is in transportation, including storage incidental to transportation
     - person knowledgeable about substance being transported (this includes hazmat services). Does not apply to dry ice
3. Air Waybill number
4. Aircraft Limitation
   - Delete either Passenger and Cargo or Cargo Aircraft Only (Delete the non-applicable).
   - If Cargo Aircraft Only (CAO) labels on the package should indicate this. Also, only CAO items can be entered on declaration
   - Airport of Destination
5. Enter the City (the freight forwarder can fill this in)

Shipment type (Radioactive/Non Radioactive)
   - Delete the non-applicable

6. Nature and Quantity of Dangerous Goods
   - UN ID Number  preceded by “UN” or “ID”

<table>
<thead>
<tr>
<th>UN ID Number</th>
<th>Proper Shipping Name</th>
<th>Class/ DIV</th>
<th>PG</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN2814</td>
<td>Infectious substance, affecting humans</td>
<td>6.2</td>
<td>-</td>
<td>620</td>
</tr>
<tr>
<td>UN2900</td>
<td>Infectious substance, affecting animals</td>
<td>6.2</td>
<td>-</td>
<td>620</td>
</tr>
<tr>
<td>UN1845</td>
<td>Carbon dioxide, solid or Dry ice</td>
<td>9</td>
<td>III</td>
<td>954</td>
</tr>
</tbody>
</table>
7. Proper Shipping Name
   • Technical names to further identify the PSN are entered in parentheses directly after the PSN.
   • No abbreviations or spelling errors are accepted. 8. Class or Division

9. Packing Group (where applicable)
   • Subsidiary risk

10. Quantity and type of packaging
    • Enter the number of packages (of the same type and content) and the type of packaging. Also enter the net quantity of dangerous goods.
    • When 2 or more different hazardous items are packed in the same outer packaging the words “All packed in one (type of packaging)” must follow all relevant entries.
    • When an overpack is used the wording “Overpack used” must follow all relevant entries.
    • Packages with overpacks used must be listed first

11. Packing Instruction
    Authorization (Special Provision A81 if body parts)

12. Additional Handling Information
    • 24 hour Emergency contact information (8.1.6.11.4) (See 2.)

    I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

14. Name/Title of Signatory Place and Date
    Signature Retain a copy for 2 years (paper or electronic)

Shipping paper approved software - 1 time user license at Labelmaster.com
www.labelmaster.com/Shop/software/shipping-paper-software/shippers-declaration-ups-fedex-forms
Or this will get you there also; www.labelmaster.com/shop/software
Package Criteria – Category B

IATA/ICAO PI 650 (UN3373)
DOT 173.199

Good quality, strong packaging to withstand “normal conditions of transport”

• Each package must contain a primary and secondary container
  
  - Both containers must be watertight.
  
  - One container must pass a 95 kPa (13.8 psi) pressure test.
  
  - In the case of multiple fragile primaries, all receptacles must be individually cushioned. (packed in a way that under normal conditions of transport, they cannot break, or leak their contents into the secondary packaging)
  
  - Absorbent is required between the primary and secondary containers and must be sufficient to absorb all liquid contents.

• An outer rigid box with a minimum dimension on one side of 100mm x 100mm (3.9 inches).
• Successfully pass 5 drop tests of 1.2 meters.

Additional requirements:

• In frozen packages the dry ice must be outside the secondary container which must remain secure after the ice dissipates. The outer package must also permit the release of the carbon dioxide gas.
• Small quantities (30ml or less) of substances in Classes 3, 8 or 9 (PG II and III) are permitted to be shipped with the infectious substances (Category B/diagnostic specimens).

Quantity Limits:

Liquid
Maximum per primary – 1 L, maximum per package – 4 L
Solid
4 kg primary and package maximum quantity

Markings: (2 part)

Diamond marking with “UN 3373” inside (1) and “Biological Substances, Category B” adjacent to diamond marking. 100mm x 100mm (50mm x 50mm min.)
Category B, PI650 Continued

For solid substances:

- the primary and secondary must be sifproof
- If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3 flammable, 8 corrosive or 9 miscellaneous in Packing Groups II and III may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.

Additional requirements:

An itemized list of contents must be enclosed between the secondary and outer packaging.

The primary and secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

Infectious substances assigned to UN3373 which are packed and marked in accordance with this packing instruction (650) are not subject to any other requirement of these Regulations except for the following:

- The name, address and telephone number of a responsible person must be provided on the air waybill or on the package.
- The classification must be in accordance to 3.6.2
- The incident reporting requirements in 9.6.1 must be met (carriers)
- The inspection for damage or leakage requirements in 9.4.1 and 9.4.2 (carriers)

Passengers and crew members are prohibited from transporting infectious substances either as or in carry-on baggage or on their person.

Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport. Retain for 1 year from issuance.

Plane Cargo Hold Inspection
Patient Specimens or Exempt Human Specimen/Exempt Animal Specimen Packaging

3.6.2.2.3.6....Packaging must meet the following conditions:

1. a leak-proof primary receptacle(s)
2. a leak-proof secondary packaging
3. an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having a minimum dimensions of 100 mm x 100 mm;

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

Marked with the words “Exempt Human Specimen” or “Exempt Animal Specimen” as appropriate. No dimensional requirement on this marking. Must be on a visible part of the outer packaging.

This is an IATA packaging regulation only Domestic Mail 500 ml per primary and total package for liquids 500 grams per primary and total package for solids Biohazard symbol on the secondary package

*Exempt Human Specimen* marking on the address side of the package
Materials of Trade Exceptions For Couriers or Those Acting as Couriers

49 CFR 173.6(a)(4) US Domestic Transport Only

A Division 6.2 material, other than a Category A infectious substance, that is contained in human or animal samples (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or is a biological product or regulated medical waste.

The material must be contained in a combination packaging. For liquids, the inner packaging must be leakproof, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging (sharps container) must be constructed of a rigid material resistant to punctures and securely closed to prevent leaks or punctures, and the outer packaging must be securely closed to prevent leaks and punctures. For solids, liquids and sharps, the outer packaging must be a strong, tight packaging securely closed and secured against shifting, including relative motion between packages, within the vehicle on which it is being transported.

Reuse, Reconditioning and Remanufacturing of Packagings

49 CFR 173.28(f)

A Division 6.2 packaging to be reused must be disinfected prior to reuse by any means effective for neutralizing the infectious substance the packaging previously contained. A secondary packaging or outer packaging conforming to the requirements of 173.196 or 173.199 need not be disinfected prior to reuse if no leakage from the primary receptacle has occurred.

IATA 5.0.2.13.5.3

Before an empty packaging which had previously contained an infectious substance is referred to the shipper, or sent elsewhere, it must be thoroughly disinfected or sterilized and any label or marking indicating that it had contained an infectious substance must be removed or obliterated.
Markings for Overpacks

49 CFR 173.25

IATA 5.0.1.5, 7.1.4

Inner packagings placed in overpacks are to be oriented in the overpack, marked and labeled. The overpack must be marked “Overpack”. In addition the overpack is marked and labeled in the same manner as the inner packaging(s). This includes:

- Proper Shipping Name
- UN ID Number
- Orientation Arrows
- Labels
- Any special handling instructions for interior packages

Duplicate All Inner Labels
Labeling and/or Markings

**Category B Marking** IATA/ICAO Packing Instruction 650. 50mm x 50mm min.
2mm line thickness, numbers and letters 6mm height

**Biohazard Symbol** (marking) refer to Occupational Health and Safety Administration (OSHA) section in the back 42 CFR 1910.1030(g)(l)(i).

**Class 6.2 Infectious Substance**

**Class 9 label** is to be placed near marking for dry ice (weight of dry ice in package).
Air Waybill

IATA 8.2

Air Waybills come in many different styles but are the most important document in air cargo transportation. The form which is approved by IATA is a straight or non-negotiable document. The instructions and conditions on the Air Waybill are closely observed. It confirms the contract between the shipper and the agent, and between the agent and the airline. It serves as the shippers proof of ownership.

IATA 8.2.1 Air Waybill(s) accompanying dangerous goods consignments must include one or more of the following statements, as applicable, on the "Handling Information" box.

a) “Dangerous goods as per attached Shippers Declaration” or “Dangerous goods as per attached DGD”;

b) “Cargo Aircraft Only” or “CAO”.

IATA 8.2.3

If a Shipper’s Declaration is not required for dangerous goods, the “Nature and Quantity of Goods” box of the Air Waybill must be shown. This is the preferred sequence:

- UN or ID number
- Proper Shipping Name
- Class or Division Number
- Number of packages
- Net quantity per package

* For UN 3373 it is only necessary to show the text “Biological Substance, Category B” and “UN 3373”

IATA 8.2.4 When Carbon dioxide, solid (dry ice) is used as a refrigerant for Class 6.2 material the details of the dry ice must be shown on the Shippers Declaration. This does not include Category B.
Handling Dry Ice, Formalin and Other Fixatives

Formalin and other fixatives 49
CFR 173.199
Packing Instruction 620 and 650
30 ml (1 oz.) of class 3, 8 and 9 or other materials in Packing Groups II or III used to stabilize or prevent degradation of the sample may be shipped with the sample. Check Material Safety Data Sheet (MSDS) before shipping.
IATA A3, A27, A48, A58, A104, A113 may apply

Wet Ice
Outer packaging, liner or overpack must be leakproof.
Sufficient absorbent for all ice in package.
Indicate “Refrigerated Medical Specimens” or relevant communication on box

Carbon Dioxide, Solid or Dry Ice
Either Proper Shipping Name acceptable

49CFR 173.217

ICAO /IATA Packing Instruction 954
UN1845
Label - Class 9 Packing

Group III

Packaging – Must be in packaging designed to release carbon dioxide gas.
• Net weight must be marked on outside of packaging.
• Advance arrangements must be made between shipper and carrier if over 5.5 lbs (2.5 kg) and shipping by air under DOT.
• DOT carriers only - 49 CFR 173.217(d) no shipping paper if marked “Dry Ice” and “Frozen Medical Specimens” (check with your carrier for their practices with dry ice)

Documentation

Shippers declaration - only necessary when dry ice is used to refrigerate dangerous goods. (Category A)

Air Waybill - does not require Packing Group (PG) and Packing Instruction (PI) number.
Operators Acceptance Checklist Dry Ice

Air Waybill

The Air Waybill contains the following:

- The words “Carbon dioxide, solid” or “Dry ice”
- The Class number “9”
- The UN Number “1845”, preceded by the prefix “UN”
- The number of packages of dry ice
- The net quantity of dry ice in kilograms

Note: The packing group “III” and packing instruction “954” are optional.

Quantity

- The quantity of dry ice per package is 200 kg or less (4.2)

Packages and Overpacks

- The number of packages containing dry ice delivered as shown on the Air Waybill
- Packages are free from damage and in a proper condition for carriage
- The packaging conforms with Packing Instruction 954 and the package is vented to permit the release of gas

Markings

(Only use this section when accepting individual packages containing dry ice)

- The words “Carbon dioxide, solid” or Dry ice” – 7.1.5.1(a)
- The UN Number “1845” preceded by prefix “UN” – 7.1.5.1(a)
- Full name and address of the shipper and consignee – 7.1.5.1(b)
- The net quantity of dry ice within each package – 7.1.5.1.(d)

Labels

- Class 9 label affixed – 7.2.3.9
- Irrelevant marks and labels removed – 7.1.1(b); 7.2.1(a) (applies to all types of packages)
Emergency Response

Safety Training

49 CFR 172.600

No person...may offer an infectious substance, or any other hazardous material for transportation, without having emergency response information on hand at all time the material is present in transportation.

49 CFR 172.602

Emergency response information means information that can be used in the mitigation of an incident involving hazardous material and as a minimum must contain the following information:

- Description and Technical name of the hazardous material
- Immediate hazards to health
- Risks of fire or explosion
- Immediate precautions to be taken in the event of an accident or incident
- Immediate methods for handling fires
- Initial methods for handling spills, leaks in the absence of fire
- Preliminary first aid measures (Legibly in English, Available away from package and Presented on a shipping paper or in a document other than a shipping paper)

IATA 9.4.2 (for carriers)

If any person responsible for the carriage or opening of packages containing infectious substances becomes aware of damage to or leakage from such a package, that person must:

- Avoid handling the package or keep handling to a minimum.
- Inspect adjacent packages for contamination and put aside any that may have been contaminated.
- Inform the appropriate public health authority or veterinary authority, and provide information on any other countries of transit where persons may have been exposed to danger; and
- Notify the shipper and/or the consignee.
Emergency Response

Mitigation procedures:

- Isolate spill or leak area immediately in all directions.
- Keep unauthorized personnel away.
- Obtain identity of substance involved if possible, and report the spill to the appropriate authorities.
- Do not touch or walk through spilled material.
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- Be particularly careful to avoid contact with broken glass or sharp objects that may cause cuts or abrasions that could significantly increase the risk of exposure.
- Damaged packages containing solid CO2 (dry ice) as a refrigerant may produce water or frost from condensation of air. Do not touch this liquid as it could be contaminated by the contents of the parcel.
- Liquid nitrogen may be present and can cause severe burns. Absorb spilled materials with earth, sand or other non-combustible material while avoiding direct contact.
- Cover damaged package or spilled material with damp towel or rag and keep wet with liquid bleach (10%) or other disinfectant. Liquid bleach will generally effectively inactivate the released substance.

DO NOT CLEAN-UP OR DISPOSE OF, EXCEPT UNDER SUPERVISION OF A SPECIALIST.

First Aid:

- Move exposed person(s) to a safe isolated area.

CAUTION: Exposed person(s) may be a source of contamination.

- Call emergency medical services.
- Remove and isolate contaminated clothing and shoes.
- In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.
- Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.
- For further assistance contact the appropriate public health authority. Ensure that medical personnel are aware of the substances involved, and take precautions to protect themselves.
Security Awareness

**CFR49 172.800** Each person who offers for transportation in commerce or transports in commerce one or more of the following hazardous materials must develop and adhere to a security plan for hazardous materials that conforms to the requirements of this subpart: (13) A select agent or toxin regulated by the Centers for Disease Control and Prevention under 42 CFR part 73 or the United States Department of Agriculture under 9 CFR part 121...

Sec. 73.3 General prohibition. An entity or individual may not possess or use in the United States, receive from outside the United States, or transfer within the United States, a select agent or toxin unless such activities are conducted for a lawful purpose and in accordance with the provisions of this part. Registration, exclusions, and exemptions are automatically revoked when any event occurs that results in an entity or individual no longer being eligible. Sec. 73.4 HHS select agents and toxins.

**HHS AND USDA SELECT AGENTS AND TOXINS**


- **HHS SELECT AGENTS AND TOXINS**
  - Abrin
  - Botulinum neurotoxins*
  - Botulinum neurotoxin producing species of *Clostridium*
  - Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)
  - *Coxiella burnetii*
  - Crimean-Congo haemorrhagic fever virus
  - Diacetoxyscirpenol
  - Eastern Equine Encephalitis virus1
  - Ebola virus*
  - *Francisella tularensis*
  - Lassa fever virus
  - Lujo virus
  - Marburg virus*
  - Monkeypox virus1
  - Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
  - Ricin
  - *Rickettsia prowazekii*
  - SARS-associated coronavirus (SARS-CoV) Saxitoxin
  - South American Haemorrhagic Fever viruses: Chapare
  - Guanarito
  - Junin
  - Machupo
  - Sabia
  - Staphylococcal enterotoxins A,B,C,D,E subtypes T-2 toxin
  - Tetrodotoxin
  - Tick-borne encephalitis complex (flavi) viruses: Far Eastern subtype
  - Siberian subtype
  - Kyasanur Forest disease virus
  - Omsk hemorrhagic fever virus
  - Variola major virus (Smallpox virus)*
  - Variola minor virus (Alastrim)*
  - Yersinia pestis*
**USDA SELECT AGENTS AND TOXINS**

African horse sickness virus  
African swine fever virus  
Avian influenza virus¹  
Classical swine fever virus  
Foot-and-mouth disease virus*  
Goat pox virus  
Lumpy skin disease virus  
*Mycoplasma capricolum*¹  
*Mycoplasma mycoides*¹  
Newcastle disease virus¹,²  
Peste des petits ruminants virus  
Rinderpest virus*  
Sheep pox virus  
Swine vesicular disease virus

**OVERLAP SELECT AGENTS AND TOXINS**

*Bacillus anthracis*  
*Bacillus anthracis* Pasteur strain  
*Brucella abortus*  
*Brucella melitensis*  
*Brucella suis*  
*Burkholderia mallei*  
*Burkholderia pseudomallei*  
Hendra virus  
Nipah virus  
Rift Valley fever virus  
Venezuelan equine encephalitis virus¹

**USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS**

*Peronosclerospora philippinensis*  
*Peronosclerosporasacchari*  
*Phoma glycinicola* (formerl *Pyrenochaeta glycines*)  
*Ralstonia solanacearum*  
*Rathayibacter toxicus*  
*Sclerophthora rayssiae Synchytrium*

---

**DOT HAZARDOUS MATERIALS REGULATIONS INFORMATION**

: 800-467-4922 x1  
endobioticum  
*Xanthomonas oryzae*

**49 CFR 172.800 Security Plans**  
**49 CFR 172.802** ...At a minimum, a security plan **must include** the following elements:

• Personnel security  
• Unauthorized access; and  
• En route security

www.phmsa.dot.gov/hazmat/security

7 CFR 331.11, 42 CFR 73.11, 9 CFR 121.11

Please contact HighQ if you need more information.  
Misc. FAA SAFETY HOTLINE  
1-800-255-1111

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This section addresses specimens received from remote locations outside of the facility in which the laboratory is located, as well as specimens referred by the laboratory to other locations. While transportation of clinical specimens may not be the responsibility of personnel under the control of the Laboratory Director, issues of tracking and specimen quality must be addressed to ensure quality laboratory results.

**GEN.40511 Phase II N/A YES NO**
Are all specimens properly packaged and labeled to indicate the general nature of the materials transported?

NOTE: All specimens must be properly packaged and labeled to indicate the general nature of the materials transported. When commercial courier services are used, the laboratory should obtain documentation from the courier service that issues related to transport of biohazardous material have been addressed.

**GEN.40512 Phase II N/A YES NO**
Does the laboratory package and ship infectious material in accordance with applicable federal, state and local regulations?

**GEN.40515 Phase II N/A YES NO**
Are transport personnel trained in appropriate safety and packaging procedures suitable to specimen type and distances transported?

NOTE: This should include issues such as adherence to regulations for transport of biohazards, use of rigid containers where appropriate, temperature control, notification procedures in case of accident or spills, etc.

**GEN.40522 Phase II N/A YES NO**
Is there documented certified training of all personnel involved in the packaging and shipping of infectious materials?

NOTE: Federal and international regulations mandate the proper packaging and transportation of infectious substances, also termed “etiologic agents.”... Specific requirements are set forth by the U.S. Public Health Service, the International Air Transport Association, the U.S. Department of Transportation and the U.S. Postal Service. These apply to domestic transportation by land, air or sea, and to international air transportation. All personnel who package specimens for shipment must satisfactorily complete certified training in these requirements.

**GEN.40530 Phase I**
For Specimens submitted to the laboratory from remote sites, is there a documented tracking system to ensure that all specimens are actually received?

Documentation should include time of dispatch and receipt, as well as condition of specimens upon receipt. An example of an acceptable tracking system is submission of a packing list (prepared by the client or courier) with each batch of client specimens, which may be checked against the specimens received by the laboratory. Some laboratory tests (e.g., coagulation assays) have limitations on time and temperature conditions between collection and analysis. This question applies to couriers/transportation systems that are part of the laboratory organization, not to outside courier systems.

**GEN.40535 Phase I N/A YES NO**
Is there an adequate process for correcting problems identified in specimen transportation, and improving performance of clients or offices that frequently submit specimens improperly?

**GEN.40540 Phase I N/A YES NO**
Is there a documented system to monitor the quality of specimens received from remote sites and collection sites not under the control of the laboratory?
Misc Info

Carrier and Package Selection

Carriers

- FedEx (not FedEx Ground)
- DHL
- UPS
- US Postal Service
- World Courier
- QuickStat
- Airnet
- Burlington Air
- Ocasa
- Emery Worldwide
- Marken Time Critical
- TNT

Supplies and Services

Cat A and B packaging

Therapak  www.therapak.com 626-599-9952 (Courier products and labels also)

Air Sea Containers

Medical Laboratory Movers/Shipper

Accelerated Moving  www.acceleratedmoving.com 614-836-1007

Specimen Integrity

Questions to consider for your shipments

- What are the effects of temperature on my specimen?
- What is the intended temperature range of specimens shipped?
- What are the external conditions my shipment may encounter considering:
  - time of year?
  - shipping point, route and delivery point climates?
  - temperature at altitude?
- How long does dry ice last in my packaging?
- Do the lock boxes keep specimens at the specified temperature?
- Does the courier know what my temperature requirements are?

For info and shipping temperature profiles contact:

Biological Specimen Transportation Association, (BSTA)  www.bsta.us info@bsta.us
Other Agencies

Centers for Disease Control (CDC) 42 CFR
- List of select agents
- Etiologic Agent label

Occupational Safety and Health Administration (OSHA) 29CFR 1910.1030
Blood borne pathogen rules including:

(g) Communication of hazards
(g)(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

United States Postal Service (USPS) 39CFR
- Does NOT permit Category A
- Category B
  - 50 ml or less per package – Double Packaging
  - 50 ml to 500 ml per package – Triple Packaging
  - Biohazard label on inner packaging
- Dry Ice- Domestic mail only
  - Via air transport, 5 lbs max, shippers declaration and Class 9 label

HighQ web training programs available
- Shipping Infectious and Biological Substances (use this manual for a discount)
- Courier Training including Blood Borne Pathogen, CAP and Best Practices

Go to www.highqllc.com email info@highqllc.com or call 724-749-4710 x 3 or 4 for more information

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Questions and Answers HighQ students can call 724-749-4710 ext 3 or 4 or email info@highqllc.com for answers to their questions.
Security Awareness

Category A - Infectious substance 6.2

Definition - A pathogen (infectious substance) capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

UN2814 - can cause disease in humans OR UN2900 - can cause disease in animals only

Packaging

<table>
<thead>
<tr>
<th>Primary container</th>
<th>Secondary container</th>
<th>Secured and not rattling around</th>
<th>Outer container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak-proof</td>
<td>Absorbent</td>
<td>Dry ice if needed</td>
<td>Has certification marking</td>
</tr>
<tr>
<td>Positively sealed</td>
<td>between with liquids</td>
<td></td>
<td>4G/CLASS 6.2/00 USA/M5070</td>
</tr>
<tr>
<td>Limits per container: 50 ml or 50 g - air 4 L or 4 Kg - cargo</td>
<td>Cushioned if multiple fragile primaries</td>
<td>Itemized list of contents</td>
<td>If dry ice - pkg can breathe</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Min area 4x4 in</td>
</tr>
</tbody>
</table>

Labeling / Markings

"Infectious substance, affecting humans UN2814" + Name, Address, phone of shipper of consignee + 24 hr phone of knowledgeable person + Net quantity of dry ice in Kg if contains dry ice on box + IF contains dry ice + Only for air shipments + IF contains >50 mls of liquid per primary container

Documentation

Shippers declaration is required for this type of shipment. See manual pg 21.

Airway bill needed for air shipments. See manual pg 30

If dry ice is used, it must be listed on the shippers declaration and the Air Waybill as:

- ID#: UN1845
- Proper Shipping name: Carbon dioxide solid OR Dry ice
- Class/division: 9
- PG: III
- Weight of dry ice
Category B - Biological Substance

Definition - A pathogen (infectious substance) which does not meet the criteria for category A

UN3373 - category B infectious substances

Packaging

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<td></td>
<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limits per container:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L per primary, 4L per package</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Kg per primary or package</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30 mls of class 3,8,9 is OK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IF BY AIR

- Absorbent between with liquids
- Leak-proof

Secured

- and not rattling around

Dry ice if needed

Itemized list of contents

If dry ice - pkg can breathe

Min area 4x4 on one side

Labeling / Markings

- Name, address, phone of responsible person
- +
- +
- +

IF contains dry ice

- +

Only for air shipments

IF contains >50 mls of liquid per primary container

Net quantity of dry ice in Kg if contains dry ice on box

Documentation

Air Waybill needed for air shipments. See manual pg 30

If dry ice is used, it must be listed on the shippers declaration and the Air Waybill as:

- ID#: UN1845
- Proper Shipping name: Carbon dioxide solid OR Dry ice
- Class/division: 9
- PG: III
- Weight of dry ice
Patient Specimens

Patient specimens that meet category A or B description must meet all requirements of those categories. A patient specimen may be EXEMPT from the regulations if there is a minimal likelihood that pathogens are present according to professional judgement based on known medical history, symptoms and individual circumstances or the source. Some examples of exempt patient specimens are: blood or urine tests to monitor things like cholesterol levels or glucose levels. Also, tests for organ function, therapeutic drug monitoring, pregnancy tests, etc.

If Patient specimens are exempt then the following apply:

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### Labeling / Markings

- “Exempt Human Specimen”
- “Exempt Animal Specimen”

- IF contains dry ice
  - Only for air shipments
- IF contains >50 mls of liquid

Net quantity of dry ice in Kg if contains dry ice on box

### Documentation

Air Waybill needed for air shipments. See manual pg 30

If dry ice is used, it must be listed on the shippers declaration and the Air Waybill as:

- ID#: UN1845
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- PG: III
- Weight of dry ice

### For overpacks (all categories):

Overpacks are when 1 or more stand alone boxes are packed in a larger box for easier or economical shipping.

The outer package must be labeled overpack and be marked and labeled the same way as the inner packages.

If it contains class 2-6 or 8 dangerous goods then the net quantity must be marked on the outer box.
Category A
Category B
Or EHS?

Substance for

Not on “The List” or not a culture of (cultures only)

Category

Exception

On “The List” or culture of something on the

Category A

Exempt Human
Package Marking and Labeling Examples

Category A box with dry ice

Infectious substances, affecting humans
UN2814

UN4G/Class USA/+CE000

Category A in Overpack Box with Dry Ice

Category B box

(Different formats acceptable as long as diamond and marking are adjacent)

Exempt Human Specimen
Exempt Animal Specimen box

Exempt Human Specimen
If any questions or concerns please contact:

HighQ, LLC
314 Fort Cherry Road
McDonald, PA 15057

724-749-4710
info@highqllc.com