

GUIDE TO CHANGES  
EFFECTIVE OCTOBER 1, 2006



Transporting  
**Infectious Substances**  
Safely

FEDERAL REGISTER

Hazardous Materials: Infectious  
Substances; Harmonization With the  
United Nations Recommendations



U.S. Department  
of Transportation

Pipeline and  
Hazardous Materials  
Safety Administration



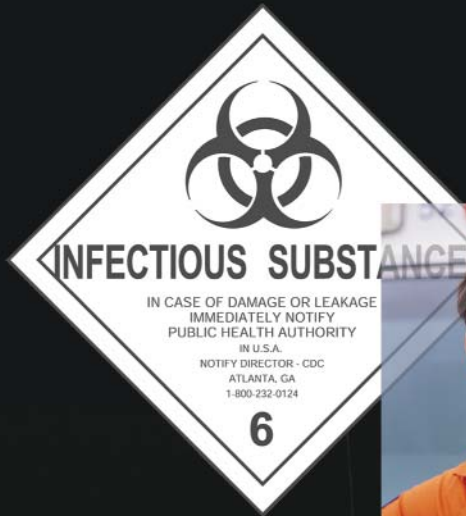
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# Introduction



## **WHY ARE INFECTIOUS SUBSTANCES REGULATED IN TRANSPORTATION?**

An infectious substance is regulated as a hazardous material under the U.S. Department of Transportation's (DOT's) Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). The HMR apply to any material DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. An infectious substance must conform to all applicable HMR requirements when offered for transportation or transported by air, highway, rail, or water.

## **NEW TRANSPORTATION REQUIREMENTS FOR INFECTIOUS SUBSTANCES**

DOT's Pipeline and Hazardous Materials Safety Administration (PHMSA) published a final rule on June 1, 2006, revising the requirements in the HMR applicable to the transportation of infectious substances. The new requirements are effective October 1, 2006.

## **CHANGES UNDER THE NEW RULE APPLY TO PARTS 171, 172, 173, AND 175 OF THE HMR**

- New classification system
  - ▶ New and revised definitions
- Revised marking requirements
- Revised packaging requirements
- New shipping paper requirements
- New security plan requirements
- New carriage by aircraft requirements

Final rule effective  
October 1, 2006

Voluntary  
compliance  
beginning  
July 2, 2006

# New Classification



# System

New classification criteria and packaging requirements are now consistent with international standards and help clarify existing requirements to promote compliance. These revisions will ensure an acceptable level of safety for the transportation of infectious substances and facilitate domestic and international transportation.

The new classifications are based on criteria developed by the UN Committee of Experts working with the World Health Organization (WHO), the U.S. Centers for Disease Control and Prevention (CDC), medical professionals, microbiologists, transportation professionals, and packaging technical experts. They are consistent with the requirements contained in the 13th and 14th editions of the United Nations Recommendations for the Transport of Dangerous Goods (UN Recommendations), the 2005-2006 edition of the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), and the International Maritime Organization (IMO) Dangerous Goods Code.

The new HMR requirements establish a two-tiered classification system for infectious substances—Category A and Category B.

Regulations are now consistent with international standards

# Category A and Category B

**DIVISION 6.2 (INFECTIOUS SUBSTANCE):** A material known or reasonably expected to contain a pathogen. A pathogen is a micro-organism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals.

**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. Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal. Category A poses a higher degree of risk than Category B.

Proper shipping  
names and  
identification  
numbers

**Infectious substances, affecting animals,**  
UN2900

**Infectious substances, affecting humans,**  
UN2814



**CATEGORY B:** An infectious substance not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes.

**PROPER SHIPPING NAME AND IDENTIFICATION NUMBER:**

**Biological substance, Category B, UN3373**

(The proper shipping names "Diagnostic Specimen" or "Clinical Specimen" may be used in place of "Biological substance, Category B" until January 1, 2007.)

New classification system: Category A and Category B

# New and Revised Definitions



## **Part 173—General Requirements for Shipments and Packagings**

In addition to Category A and Category B, there are other new and revised definitions in §173.134.

**BIOLOGICAL PRODUCT:** 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.

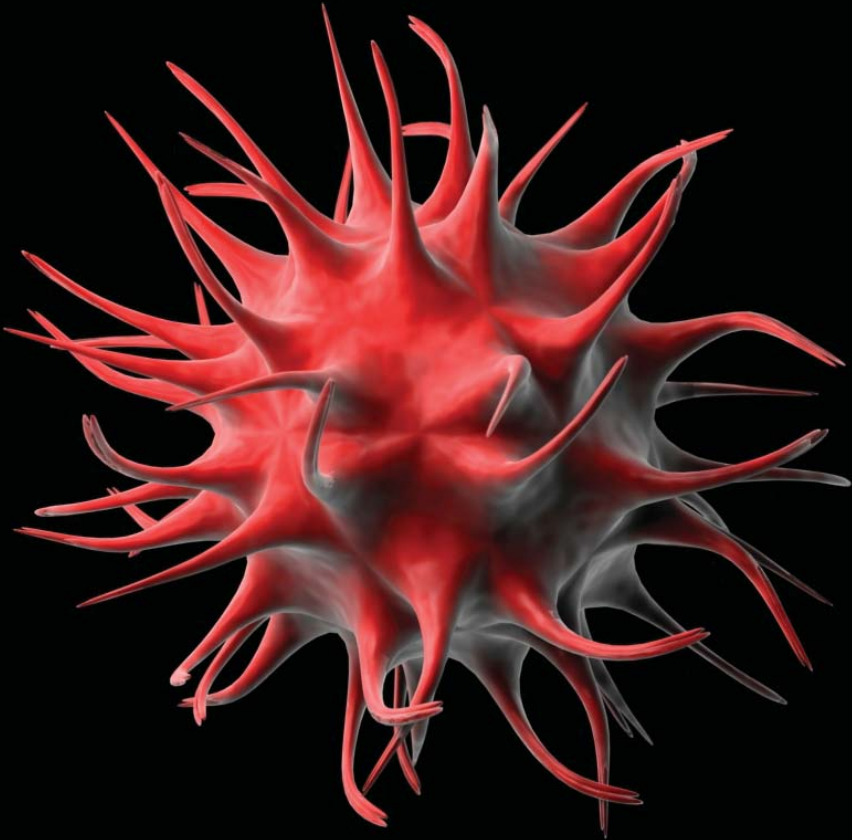
**CULTURE:** An infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimen as defined below.

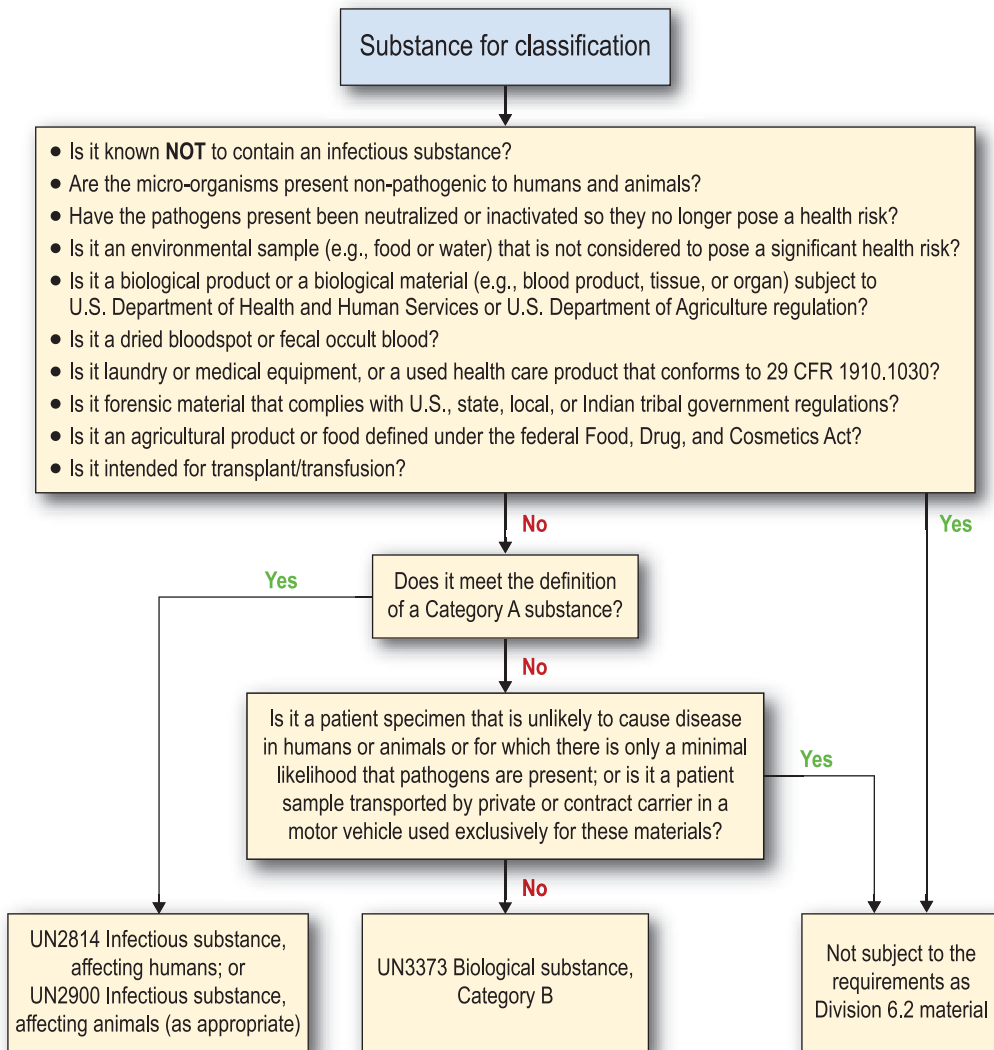
**PATIENT SPECIMEN:** Human or animal materials collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimen includes excreta, secretions, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g., transwabs, culture media, and blood culture bottles).

**EXCEPTIONS:** A complete listing of materials excepted from regulation as Division 6.2 materials under the HMR is found in §173.134(b).

New definitions  
Division 6.2  
Infectious  
Substance  
(§173.134)

# Classification Process







# Examples of Category A Infectious UN2814, Infectious Substances Affecting

## MICRO-ORGANISM

Bacillus anthracis (cultures only)  
Brucella abortus (cultures only)  
Brucella melitensis (cultures only)  
Brucella suis (cultures only)  
Burkholderia mallei—Pseudomonas mallei—Glanders  
(cultures only)  
Burkholderia pseudomallei—Pseudomonas pseudomallei  
(cultures only)  
Chlamydia psittaci—avian strains (cultures only)  
Clostridium botulinum (cultures only)  
Coccidioides immitis (cultures only)  
Coxiella burnetti (cultures only)  
Crimean-Congo hemorrhagic fever virus  
Dengue virus (cultures only)  
Eastern equine encephalitis virus (cultures only)  
Escherichia coli, verotoxigenic (cultures only)  
Ebola virus  
Flexal virus  
Francisella tularensis (cultures only)  
Guanarito virus  
Hantaan virus  
Hantaviruses causing hemorrhagic fever with renal syndrome  
Hendra virus  
Herpes B virus (cultures only)  
Human immunodeficiency virus (cultures only)  
Highly pathogenic avian influenza virus (cultures only)

Examples of  
Category A  
infectious  
substances

# Substances:

## Humans

Japanese Encephalitis virus (cultures only)  
Junin virus  
Kyasanur forest disease virus  
Lassa virus  
Machupo virus  
Marburg virus  
Monkeypox virus  
Mycobacterium tuberculosis (cultures only)  
Nipah virus  
Omsk hemorrhagic fever virus  
Poliovirus (cultures only)  
Rabies and other lyssaviruses (cultures only)  
Rickettsia prowazekii (cultures only)  
Rickettsia rickettsia (cultures only)  
Rift Valley fever virus (cultures only)  
Russian spring-summer encephalitis virus (cultures only)  
Sabia virus  
Shigella dysenteriae type I (cultures only)  
Tick-borne encephalitis virus (cultures only)  
Variola virus  
Venezuelan equine encephalitis virus (cultures only)  
Vesicular stomatitis virus (cultures only)  
West Nile virus (cultures only)  
Yellow fever virus (cultures only)  
Yersinia pestis (cultures only)

List provided as  
**guidance only**

List is **NOT**  
all inclusive

# Examples of Category A Infectious

## UN2900, Infectious Substances Affecting





# Substances:

## *Animals Only*

### **MICRO-ORGANISM**

African swine fever virus (cultures only)  
Avian paramyxovirus Type 1—Velogenic Newcastle disease virus (cultures only)  
Classical swine fever virus (cultures only)  
Foot and mouth disease virus (cultures only)  
Lumpy skin disease virus (cultures only)  
Mycoplasma mycoides—Contagious bovine pleuropneumonia (cultures only)  
Peste des petits ruminants virus (cultures only)  
Rinderpest virus (cultures only)  
Sheep-pox virus (cultures only)  
Goatpox virus (cultures only)  
Swine vesicular disease virus (cultures only)

List provided as  
**guidance only**

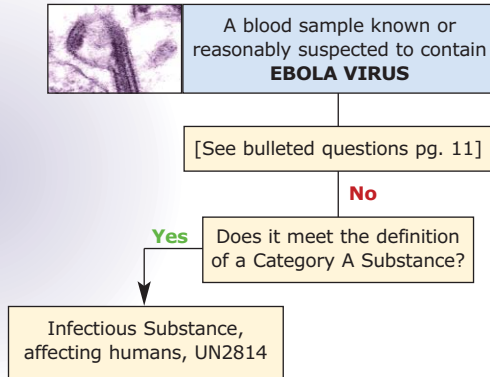
List is **NOT**  
all inclusive

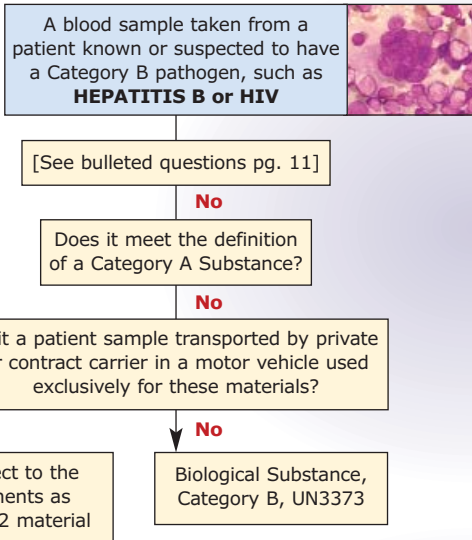
# Classification Scenarios

## SCENARIO 1

### Appropriate classification:

Infectious Substance,  
affecting humans,  
UN2814

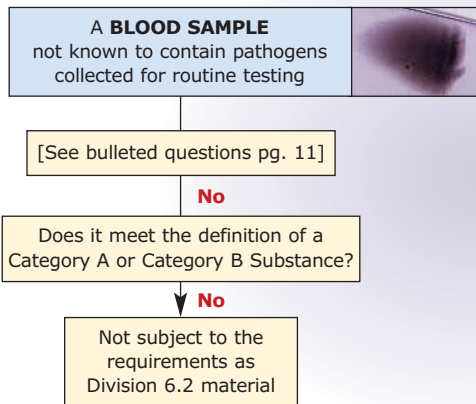




### SCENARIO 3

#### Appropriate classification:

Biological Substance, Category B, UN3373 (unless transported by private or contract carrier by motor vehicle)



### SCENARIO 4

#### Appropriate classification:

Not subject to the Hazardous Materials Regulations



## **General Information**

**Paragraph D. Exceptions for Certain Shipments  
Federal Register/Vol. 71, No. 106/June 2, 2006/  
page 32248.**

Specimen packages marked as “Exempt human specimen” or “Exempt animal specimen” according to the ICAO Technical Instructions **are not** regulated under the HMR. In the United States, the mark “Exempt Human/Animal Specimen” is an indication that there is no infectious substance in the package. Packages bearing these marks may be accepted by an air carrier that has made a business decision not to accept hazardous materials.

**§171.15 and §171.16 Incident reporting.**

You must report any release of an infectious substance (Category A or B) in any mode of transportation to the Department of Transportation. See §171.15 for telephonic and §171.16 for written report requirements.

“Exempt human specimen” and  
“Exempt animal specimen”

Incident reporting




# Part 172—Hazardous Materials

Symbols (1)	Hazardous Materials Descriptions and Proper Shipping Names (2)	Hazard Class or Division (3)	Identification Numbers (4)	PG (5)	Label Codes (6)	Special Provisions (§172.102) (7)	(8) Packaging (§173.***)			(9) Quantity Limitations		(10) Vessel Stowage	
							Exceptions (8A)	Non-bulk (8B)	Bulk (8C)	Passenger aircraft/rail (9A)	Cargo aircraft only (9B)	Location (10A)	Other (10B)
	Biological substance, Category B	6.2	UN3373			A82	134	199	None	4L or 4kg	4L or 4kg	A	40
G	Infectious substances, affecting animals <i>only</i>	6.2	UN2900		6.2	A82	134	196	None	50mL or 50g	4L or 4kg	B	40
G	Infectious substances, affecting humans	6.2	UN2814		6.2	A82	134	196	None	50mL or 50g	4L or 4kg	B	40

Added  
“Biological  
substance,  
Category B”

# Table Changes

## §172.101 Hazardous materials table.

- Removed  "Diagnostic specimen"
- Added  "Biological substance, Category B"
- Revised  "Infectious substances, affecting animals *only*"
- "Infectious substances, affecting humans"
- "Toxins, extracted from living sources, liquid, n.o.s."
- "Toxins, extracted from living sources, solid, n.o.s."

§172.101  
Removed  
"Diagnostic  
specimen"


# Part 172—Special Hazardous Materials






# Provisions, Communication Changes

## §172.102 Special provisions.


Removed  Special provision A81 pertaining to quantity limits (see §173.199)

## §172.200(b)(4) and §172.203(k) Shipping Papers.

Revised  Applicability

Added  Technical name “Suspected Category A” for unknown substances using UN2814 or UN2900

## §172.301 Marking.

Revised  No technical name on outer package

§172.102  
Removed  
special  
provision A81


Subparts C and  
D of Part 172  
revisions and  
additions

**Part 172**



# – Security Plans

## §172.800 Purpose and Applicability.

Revised  Persons who offer for transportation or transport select agents and toxins regulated by the CDC under 42 CFR Part 73 **or** USDA under 9 CFR Part 121 must develop and implement **security plans** in accordance with Subpart I of Part 172 of the HMR.

# Part 173—General Requirements for Shipments



# and Packagings Changes

Includes changes pertaining to:

- §173.6 Materials of trade (MOT)
- §173.24a Non-bulk packagings
- §173.134 Definitions—see page 8
- §173.134(b) Exceptions
- §173.199 Category B infectious substances

## **§173.196 Category A infectious substances.**

Added  Category A infectious substances

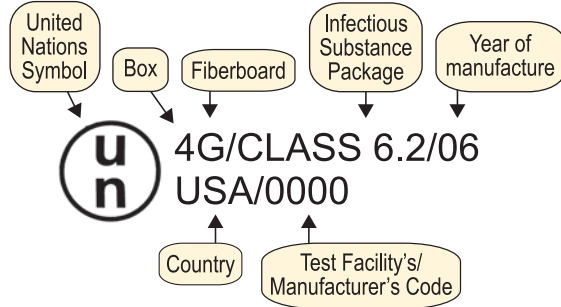
Changes to  
non-bulk  
packagings

# Packing and Labeling of Category A

## PACKAGING FOR A CATEGORY A INFECTIOUS SUBSTANCE

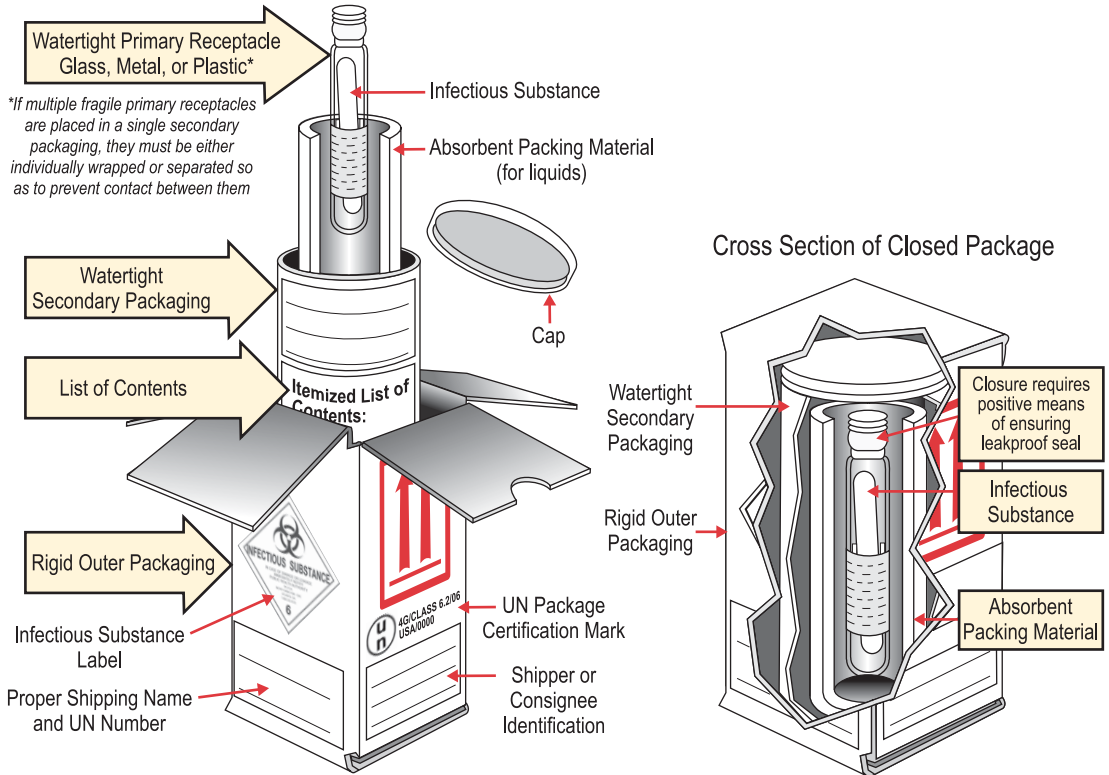
- Must meet the test standards of §178.609 and must be marked in conformance with §178.503(f)
- Is a triple packaging consisting of
  - ▶ Primary watertight receptacle
  - ▶ Watertight secondary packaging
  - ▶ Rigid outer packaging

## SAMPLE OF UN PACKAGE CERTIFICATION MARK



Additional packaging requirements can be found in §173.196(b)


# Infectious Substances

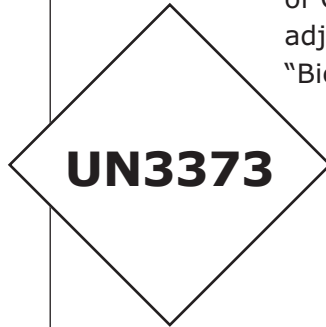


- Note 1:** The smallest external dimension of the outer packaging must not be less than 100 mm (3.9 inches)
- Note 2:** The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa
- Note 3:** Follow package manufacturer's closure instructions

# Packing and Marking of Category B

## §173.199 Category B infectious substances.

Revised  Required marking on outer package of Category B infectious substance adjacent to proper shipping name "Biological substances, Category B"



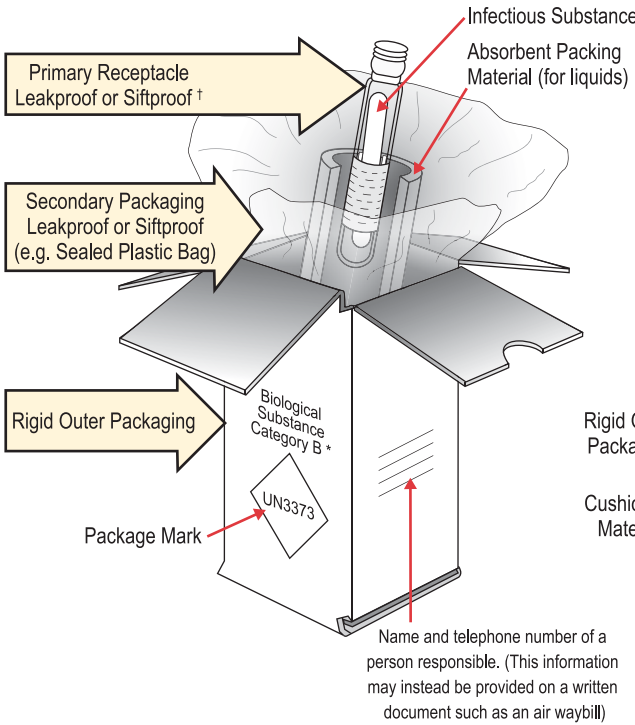
Additional  
packaging  
requirements  
can be found  
in §173.199

**Note 1:** At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (3.9 inches)

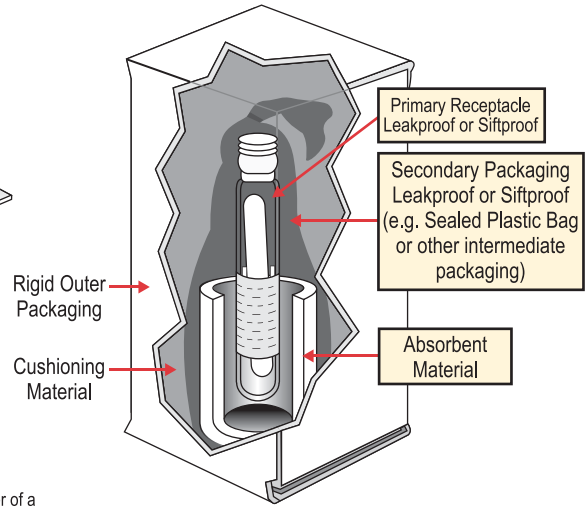
**Note 2:** For liquid shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa



# Infectious Substances



Cross Section of Closed Package



\* The proper shipping names "Biological Substance, Category B"; "Clinical Specimen"; and "Diagnostic Specimen" are authorized until December 31, 2006. From January 1, 2007 only the proper shipping name "Biological Substance, Category B" will be authorized.

† If multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact


**Note:** Follow package manufacturer's closure instructions



# Part 175—Carriage

# by Aircraft Changes

## **§175.630 Special requirements for Division 6.1 (poisonous) material and Division 6.2 (infectious substances) materials.**

Added  Paragraph (c) requirement to inspect each package, overpack, pallet, or unit load device containing a 6.2 material for signs of leakage. If evidence of leakage is found, the cargo compartment hold where the 6.2 material was stowed is required to be disinfected by any means that makes the release of the 6.2 material ineffective at transmitting disease.



# Where to Learn More

For information about other  
Hazmat Publications

**Write:**

U.S. Department of Transportation  
Pipeline and Hazardous Materials Safety  
Administration  
1200 New Jersey Avenue, SE, PHH-50  
Washington, DC 20590-0001

**Fax:** (202) 366-7342

**E-mail:** [training@dot.gov](mailto:training@dot.gov)

**Phone:** (202) 366-2301

**Or visit our web site:**

<http://hazmat.dot.gov>

E-mail: [infocntr@dot.gov](mailto:infocntr@dot.gov)

