



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

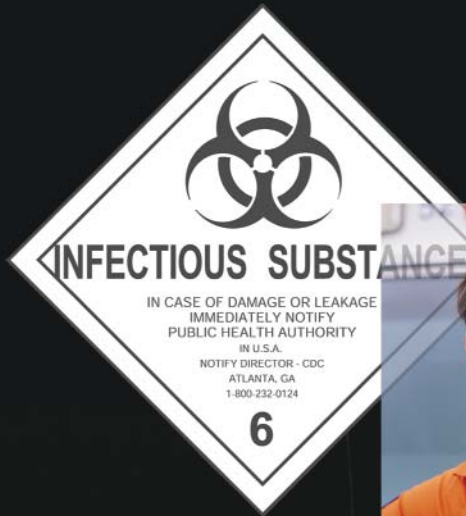
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Introduction



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

A hand is shown holding a test tube containing a pink liquid. In the background, there are several other test tubes and a beaker, all containing similar pink liquids. The scene is set against a dark blue background.

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.

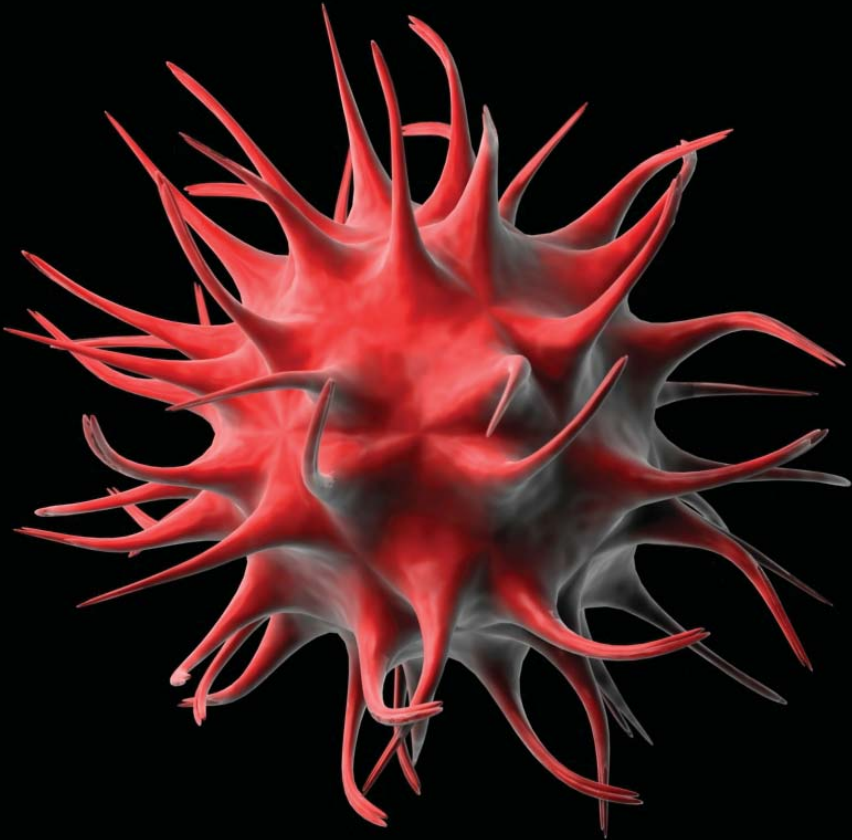
CULTURE: An infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimen as defined below.

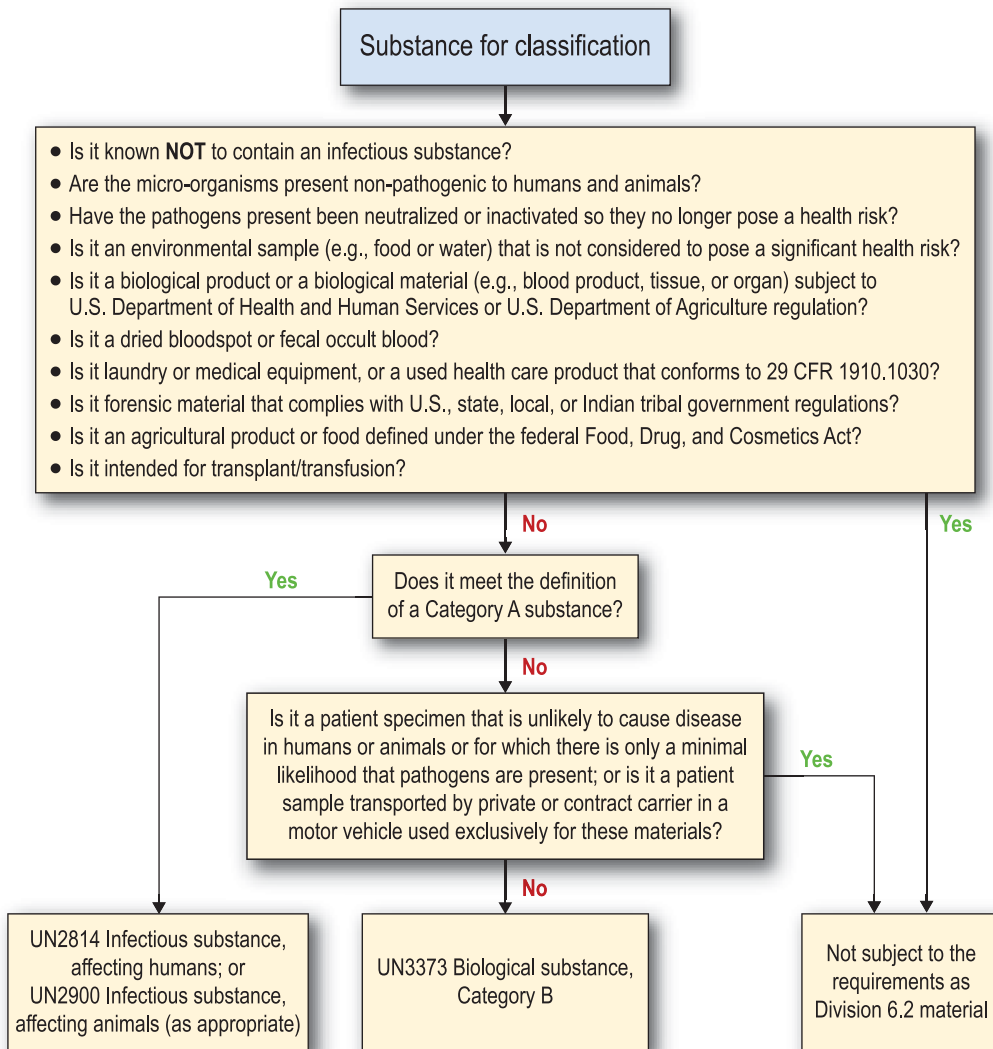
PATIENT SPECIMEN: Human or animal materials collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimen includes excreta, secreta, blood and its components, tissue and tissue swabs, body parts, and 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

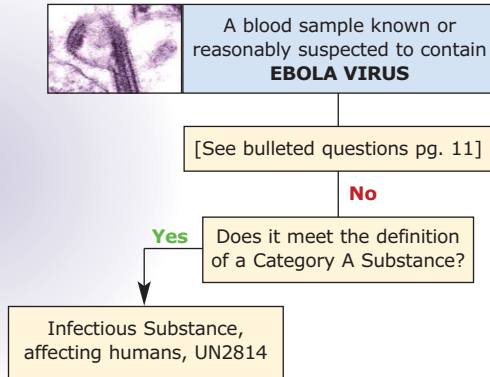
List is **NOT**
all inclusive

Classification Scenarios

SCENARIO 1

Appropriate classification:

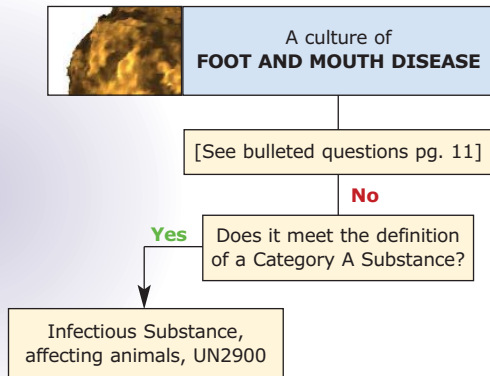
Infectious Substance,
affecting humans,
UN2814

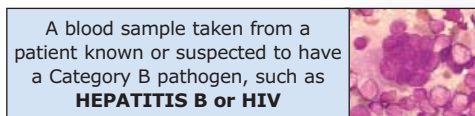


SCENARIO 2

Appropriate classification:

Infectious Substance,
affecting animals,
UN2900





[See bulleted questions pg. 11]

No

Does it meet the definition of a Category A Substance?

No

Yes

Is it a patient sample transported by private or contract carrier in a motor vehicle used exclusively for these materials?

No

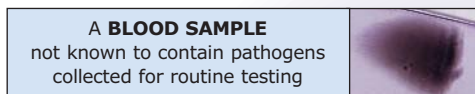
Not subject to the requirements as Division 6.2 material

Biological Substance, Category B, UN3373

SCENARIO 3

Appropriate classification:

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



[See bulleted questions pg. 11]

No

Does it meet the definition of a Category A or Category B Substance?

No

Not subject to the requirements as Division 6.2 material

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	
							Excep- tions (8A)	Non- bulk (8B)	Bulk (8C)	Passenger aircraft/rail (9A)	Cargo air- craft 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

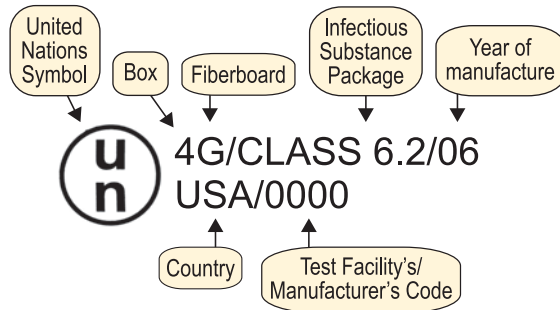
Changes to
non-bulk
packagings

Packing and Labeling of Category A

PACKAGING FOR A CATEGORY A INFECTIOUS SUBSTANCE

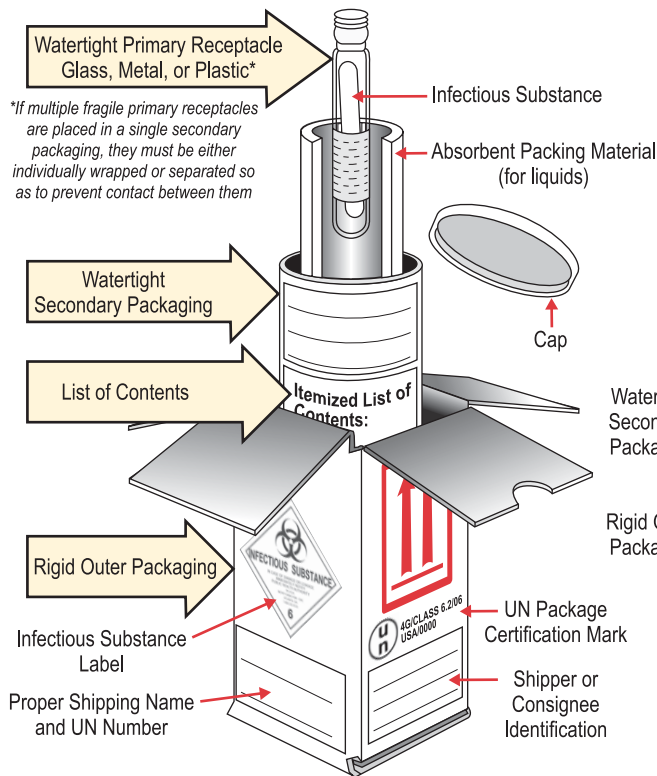
- Must meet the test standards of §178.609 and must be marked in conformance with §178.503(f)
- Is a triple packaging consisting of
 - ▶ Primary watertight receptacle
 - ▶ Watertight secondary packaging
 - ▶ Rigid outer packaging

SAMPLE OF UN PACKAGE CERTIFICATION MARK

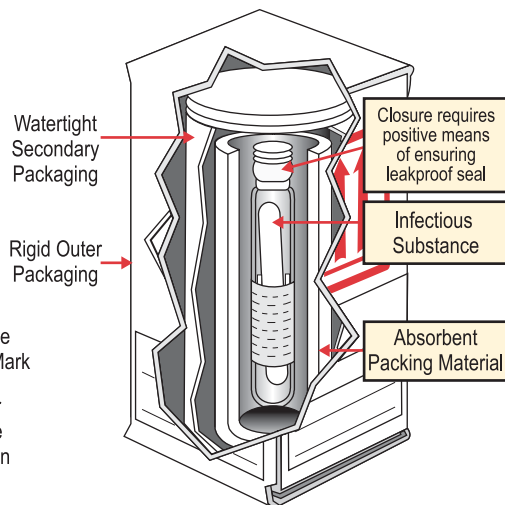


Additional
packaging
requirements
can be found
in §173.196(b)

Infectious Substances



Cross Section of Closed Package



Note 1: The smallest external dimension of the outer packaging must not be less than 100 mm (3.9 inches)

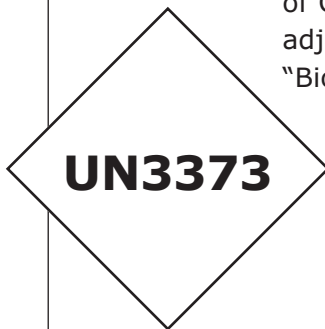
Note 2: The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa

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"

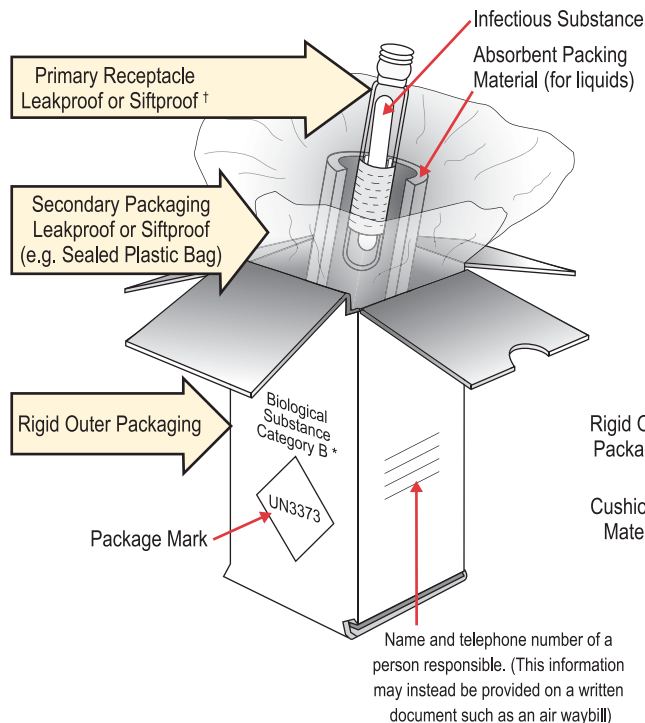


Additional
packaging
requirements
can be found
in §173.199

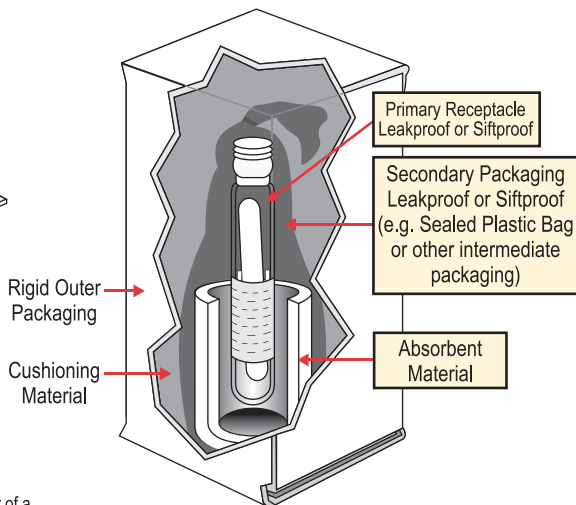
Note 1: At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (3.9 inches)

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:

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