



Transporting Infectious Substances Safely

William Stevens
US DOT/PHMSA/OHME
Southern Region
404-832-1140

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Infectious Substances Guide





Objective

- Provide a general overview of the regulatory requirements for transporting Division 6.2 materials:
 - Definitions and Package Selection
 - Marking and Labeling
 - Shipping Papers and Emergency Response Information
 - Security and Training
- Identify requirements for Regulated Medical Waste



U.S. DOT Hazardous Materials Regulations (HMR)

The HMR govern the packaging and safe transportation of hazardous materials by air, highway, rail, and water (except bulk transportation onboard vessel)





Other Federal Regulations Governing Safe Transport of Infectious Substances

- Department of Health and Human Services (HHS)
 - 42 CFR Parts 72 and 73 – Interstate Shipment of Etiologic Agents and Select Agents and Toxins
 - Agriculture 7 CFR Part 331
 - Plant/Animal 9 CFR Part 121
- Department of Labor/OSHA
 - 29 CFR, Section 1910.1030 – Bloodborne Pathogens



International Regulations

- The International Civil Aviation Organization (ICAO)
 - ICAO Technical Instructions for the safe Transport of Dangerous Goods
- The International Maritime Organization (IMO)
 - International Maritime Dangerous Goods Code (IMDG Code)
- The HM226A Final Rule on Infectious Substances
 - Brought HMR in harmonization with international documents



Division 6.2 Materials

- Infectious Substance
- Biological Product
- Cultures and Stocks
- Regulated Medical Waste



Infectious Substance Definition

- A material known or suspected to contain a pathogen:
 - a microorganism (including bacteria, viruses, parasites, fungi) or other agent, that can cause disease in humans or animals.
- Infectious substances must be assigned to one of four UN Identification numbers:

UN2814 UN2900 UN3373 UN3291



Category A Infectious Substance

- Identified as:
 - Infectious substances, affecting animals *only*, UN2900; and
 - Infectious substances, affecting humans, UN2814



Division 6.2 Definitions & Packaging (49 CFR 173.134 & 173.196)

Division 6.2 -

Known or reasonably expected to contain a pathogen that can cause disease in humans or animals

Category A - a form capable of causing permanent disability or life threatening or fatal disease in healthy humans or animals when exposure (i.e., release outside packaging resulting in physical contact with humans or animals) to it occurs

Category A Package:

UN standard triple packaging meeting the requirements in § 173.196

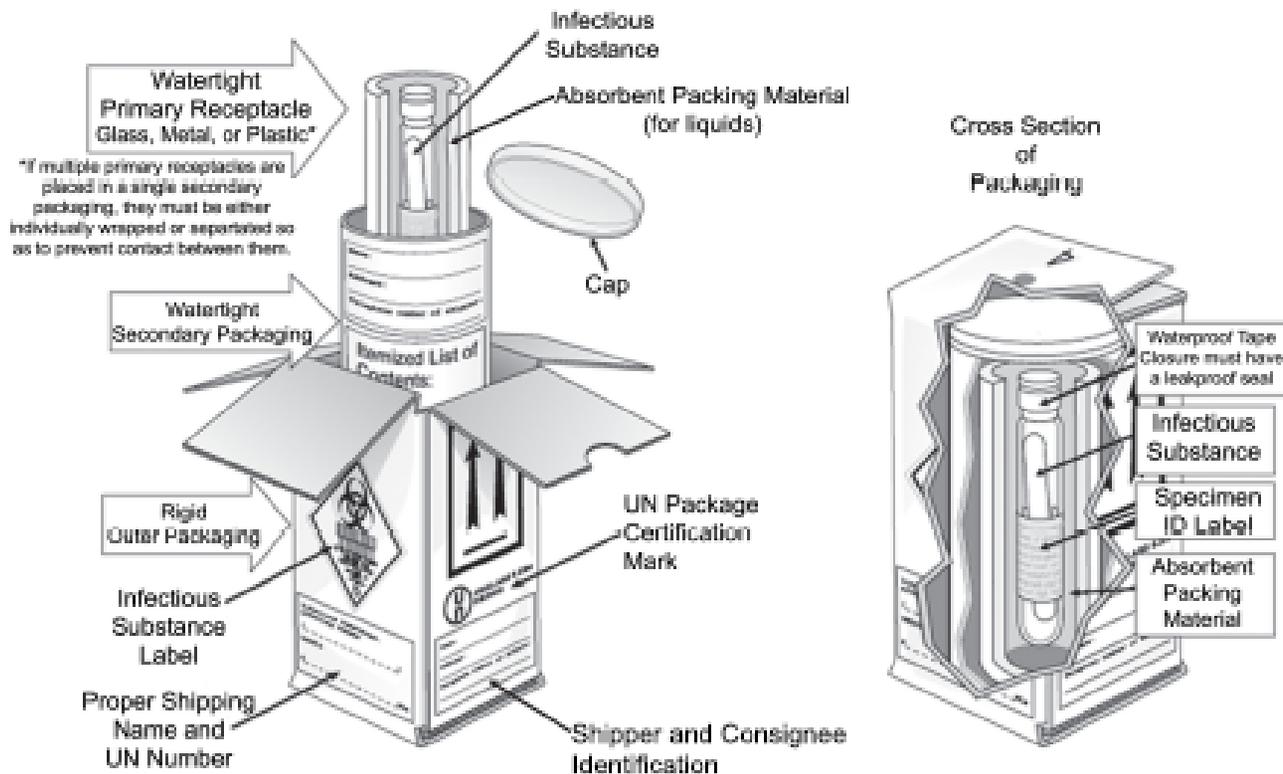
Cat. A RMW must be called "Infectious Substance"

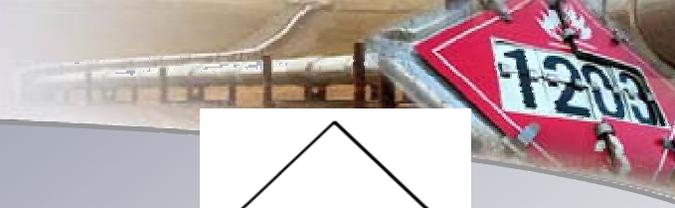
Suspected unknown Cat. A must have "Suspected Category A Infectious Substance" in place of technical name on shipping paper & should not be marked on outside of package



Packing and Labeling of Category A Infectious Substances

(See Packing Instruction 602)





Division 6.2 (49 CFR 173.134 & 173.199)

Category B – not in a form generally capable of causing permanent disability or life threatening or fatal disease in healthy humans or animals when exposure occurs; incl. Cat B trans. for diagnostic or investigational purposes.

“UN 3373, Biological substance, Category B”

RMW must be assn'd
UN3291

Non-spec. triple packaging:

Primary receptacle –

- Leakproof/Siftproof
- Packed so they cannot break, puncture or leak
- ≤ 1 L liquids by aircraft
- Indiv. wrapped if fragile

Secondary packaging –

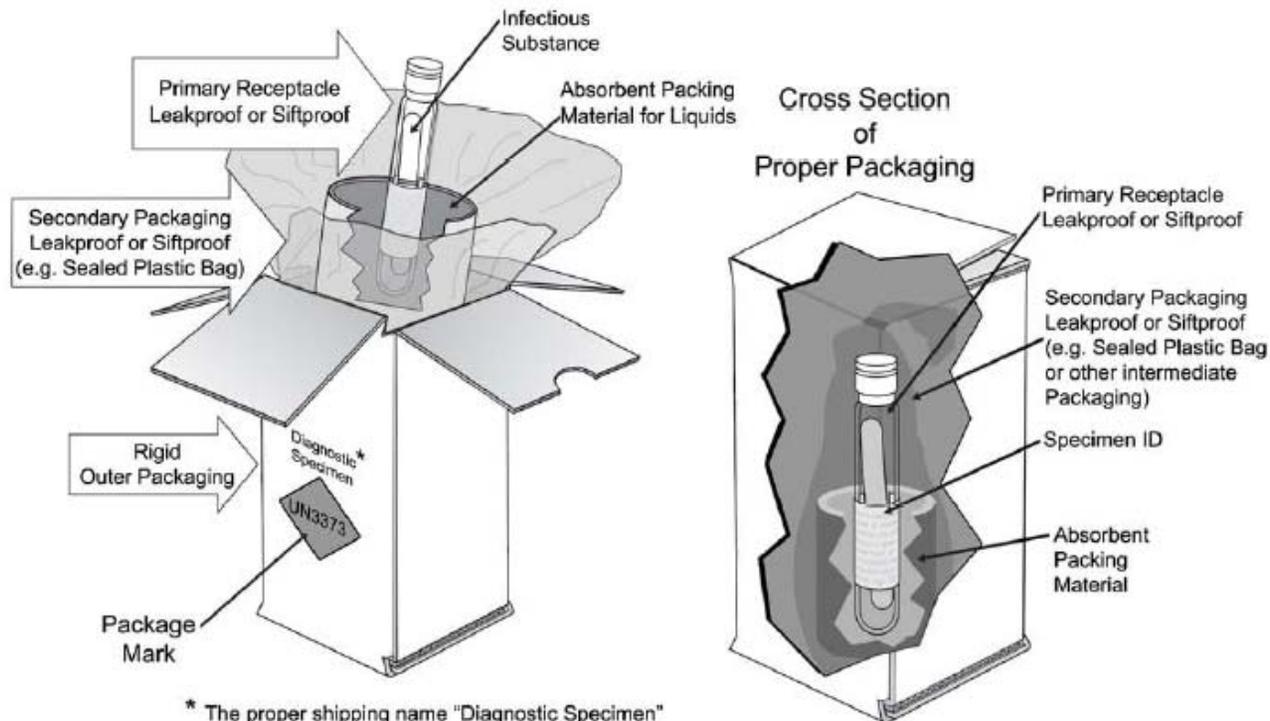
- Siftproof for solids
- Absorbent material for all contents
- Secured w/in outer pkg.
- Primary or Secondary must w/stand changes in pressure & temperature

Outer packaging -

- Capable of Passing drop test at 1.2 m
- 4 L/4 kg limit for aircraft



Packing and Labeling of Category B Infectious Substances



* The proper shipping name "Diagnostic Specimen" or "Clinical Specimen" must be indicated. Technical name is not necessary.



Biological Products (49 CFR 173.134 & 173.199)

A virus, therapeutic serum, toxin, anti-toxin, vaccine, blood, blood component or derivative, allergenic or analogous product or arsphenamine (chemo. agent) or its derivative or any other trivalent arsenic compound, applicable to the prevention, treatment or cure of human or animal disease or condition

Includes material subject to 42 U.S.C. 262 or 21 U.S.C. 151-159

If known or reasonably expected to contain a Cat. A or B infectious substance

- **Must be assn'd identification no. UN 2814, UN 2900, or UN 3373**



Cultures

49 CFR 173.134, 173.196, 173.199

An infectious substance containing a pathogen that is intentionally propagated. It does not include a human or animal patient specimen as defined in §173.134(a)(4)

Packaging:

Suspected Category A goes in 173.196 pkg

Suspected Category B & cultured patient specimens go in 173.199 pkg

Waste, concentrated stock culture of Cat. B may be trans as RMW in rigid non-bulk pkg mtg general pkg & OSHA bloodborne reqs. & trans by private or contract carrier in exclusive use RMW vehicle



Patient Specimen Definition

- Human or animal material (excreta, secreta, blood, tissue, tissue swabs) transported for diagnostic or investigational purposes
- Transported as Category B infectious substances
 - not considered capable of causing permanent disability or life-threatening or fatal disease in healthy humans or animals if exposure occurs



Regulated Medical Waste (49 CFR 173.134 & 173.197)

A waste or reusable material derived from medical treatment of animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production and testing of biological products. (Cat. A is assn'd to UN 2814 or UN 2900)

***Outer packagings* for non-bulk, Large, and non-specification must be rigid & comply with 173.Subpart B**

Untreated concentrated stock cultures of Cat. A may not be trans. in a Cart or BOP

Nonbulk-

- **PG II packaging (49 CFR Part 178)**
- **Puncture resistant for sharps**

Bulk - Inner pkgs. meet §178.197(e)

Large -

UN Metal (50A, 50B & 50 N) & Plastic (50H)

Meets IBC perform. requirements

Wheeled Cart & Bulk Outer Packaging

Smooth non-porous interior

Used exclusively for RMW



Exceptions

- A material that is unlikely to cause disease in humans or animals
- Non-infectious biological materials from humans, animals, or plants
- A material containing neutralized or inactivated pathogens and no longer pose a health risk
- Blood collected for transfusion or preparation of blood products sent for testing (unless believed to contain an infectious substance)



Exceptions (cont'd)

- Laundry, medical equipment conforming to OSHA regs 29 CFR 1910.1030
- Any waste or recyclable material, other than RMW
- Corpses, remains, and anatomical parts intended for interment, cremation, or medical research



Used Health Care Products

- Products not conforming to CFR1910.1030 returned to manufacturer
- Triple non-spec package
- BIOHAZARD mark on primary and secondary packaging
- Itemized list
- No shipping paper, label, or emergency response information



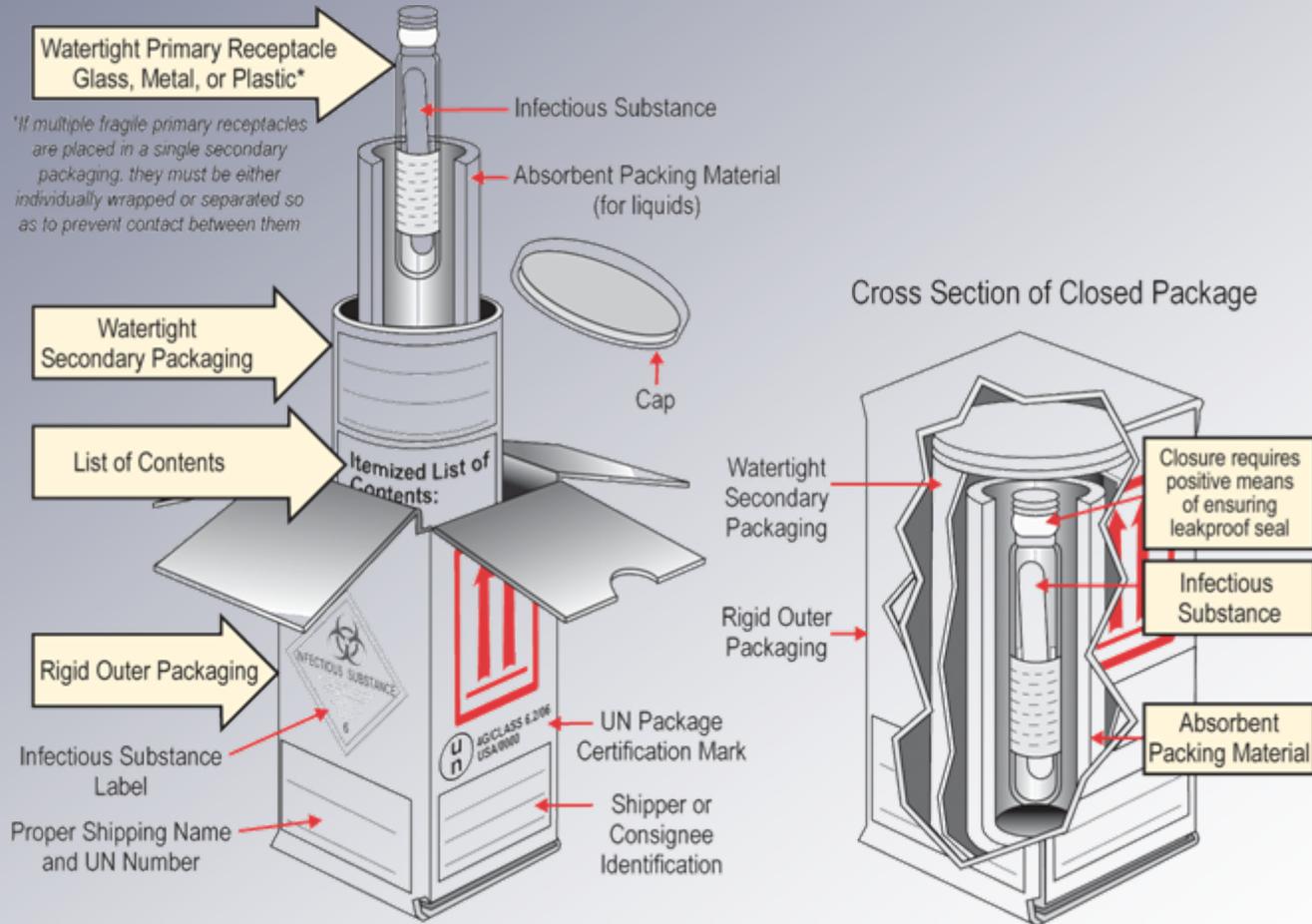


Packaging Requirements

173.24	General Packaging
173.24a	Requirements for all HAZMAT
173.24a(c)	Changes regarding Infectious Substances and mixed contents
	Exceptions for:
173.134(b)	Division 6.2 Packaging Regulated Medical Waste
173.134(c)	
173.196	Category A Infectious Substance
173.197	Regulated Medical Waste
173.199	Category B Infectious Substance
178.609	6.2 Packaging Tests

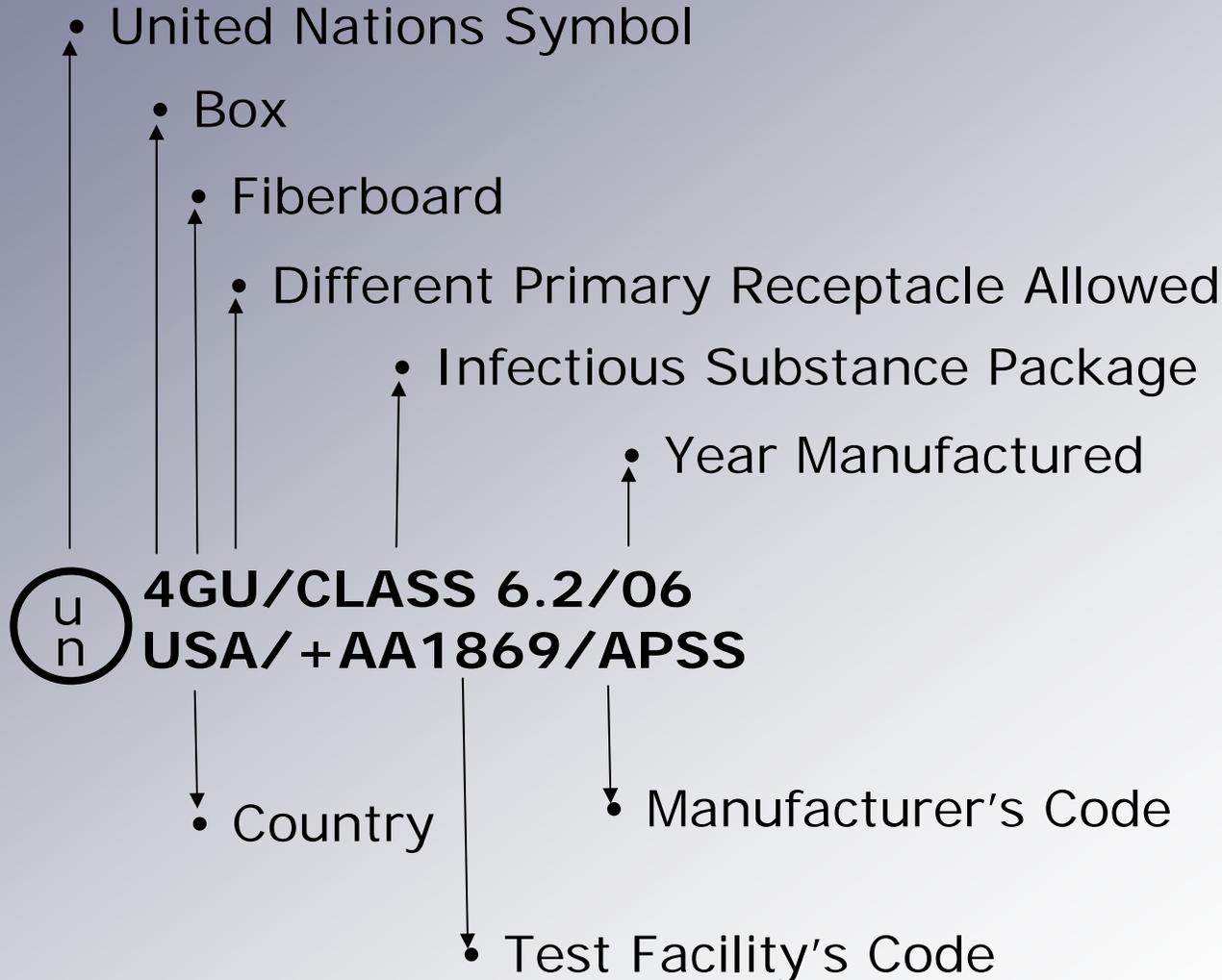


Category A Packaging – UN Marking



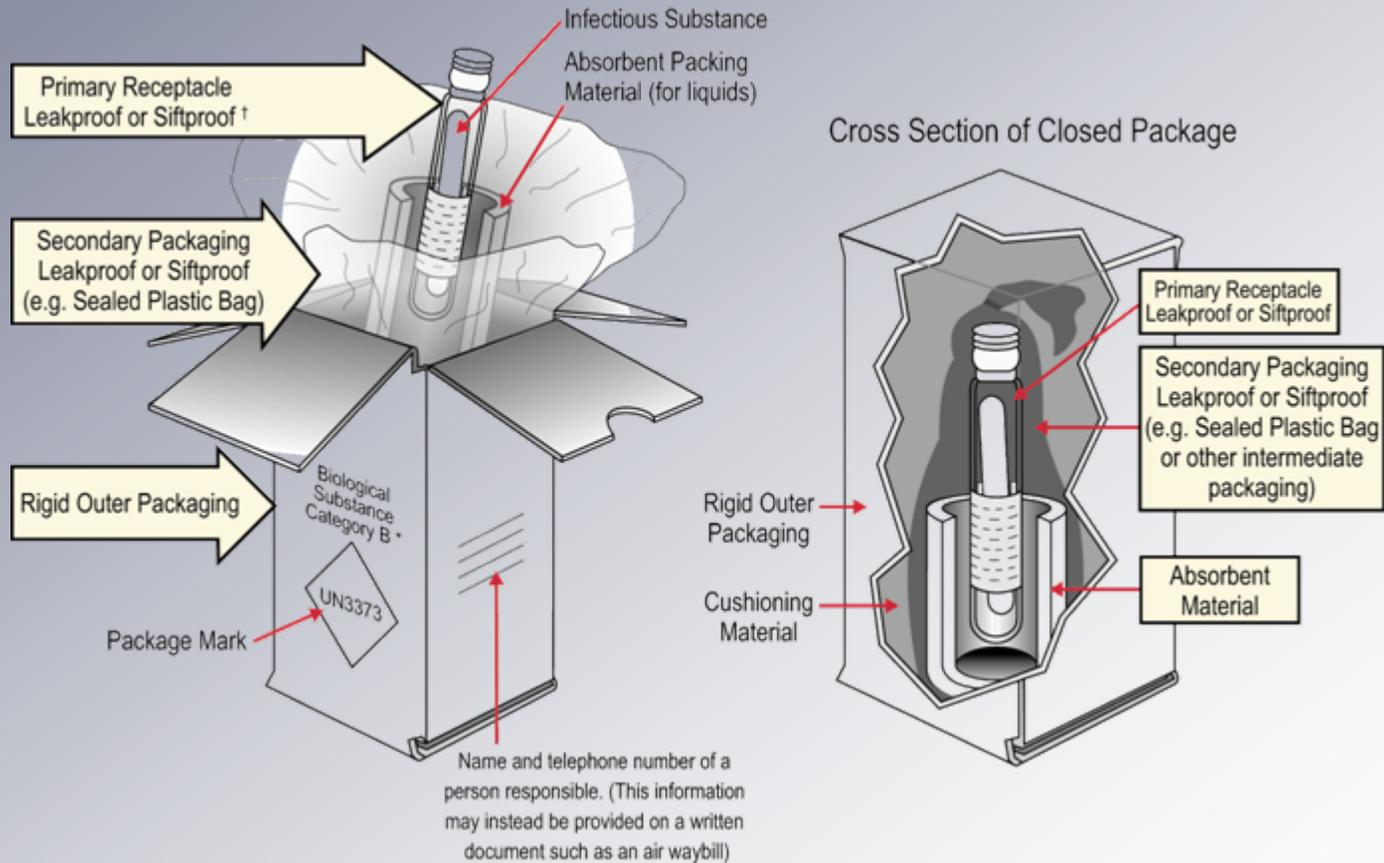


UN Packaging – Division 6.2 Category A





Category B Packaging – No UN Marking





Regulated Medical Waste (RMW) Packaging

Non-Bulk Pkgs

- Rigid
- Leak resistant
- Impervious to moisture
- Burst, tear, and break resistant
- Puncture resistant for sharps
- Sealed to prevent leaks
- Meets UN PG II specs of Part 178
(*173.134(c)) Exception of 173.197



Regulated Medical Waste Exceptions

173.134(c)

- Non-bulk RMW transported by private or contract carrier
 - No Infectious Substance label if OSHA BIOHAZARD marked
 - Non-spec packaging and OSHA packaging (other than waste concentrated stock culture of an infectious substance, CAT A)
- Cultures/stocks in OSHA packaging and *vehicle used exclusively to transport RMW* (Category B infectious substance)



Regulated Medical Waste

- Bulk packaging 173.197
 - Large packaging (UN spec- 50 series)
 - BOP (non-spec)
 - Biohazard Mark
 - CART – requires drop test capability at PG II level (3.9 ft/1.2 m)
- Inner packaging
 - Solids: plastic film bag (ASTM performance tests - Marked)
 - Liquids: rigid, general packaging requirements in Part 173 (not over 5 gallons)
 - Sharps: puncture-resistant, PG II performance level if over 20 gallons; closure procedures





From Regulated to Non-Regulated

Once sterilized, regulated medical waste is no longer considered a Division 6.2 material



RMW entering autoclave unit



Proper Shipping Names and Identification Numbers

- Biological substance, Category B, UN3373
- Category A infectious substance:
 - Infectious substances, affecting animals, *only*, UN2900
 - Infectious substances, affecting humans, UN2814
- Regulated medical waste, n.o.s., UN3291



Marking and Label Requirements

- Category A
 - Proper shipping name, UN 2814 or UN 2900 (as applicable)
 - Infectious Substance Label identification
 - Dry Ice ID info (as applicable)
 - Orientation arrows (as applicable)
- Category B
 - Proper shipping name
 - UN 3373 marking (NLT 2 " on side)
 - Name and telephone number of responsible person (may be placed on separate document such as air waybill)
 - Orientation arrows (as applicable)



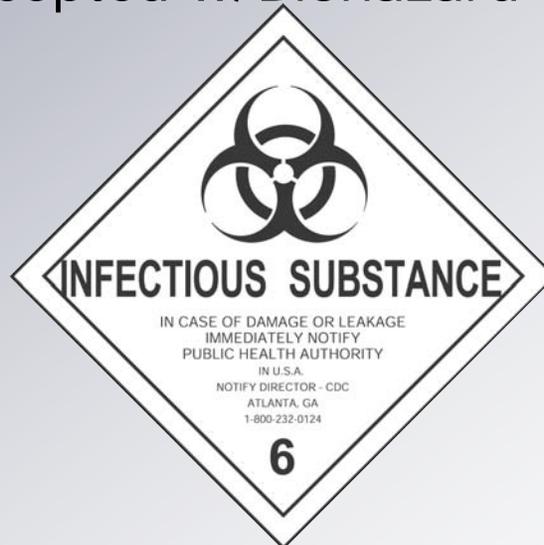
Marking and Label Requirements (cont'd)

- Regulated medical waste
 - Proper shipping name
 - UN 3291
 - OSHA BioHazard Symbol
 - Orientation arrows (as applicable)



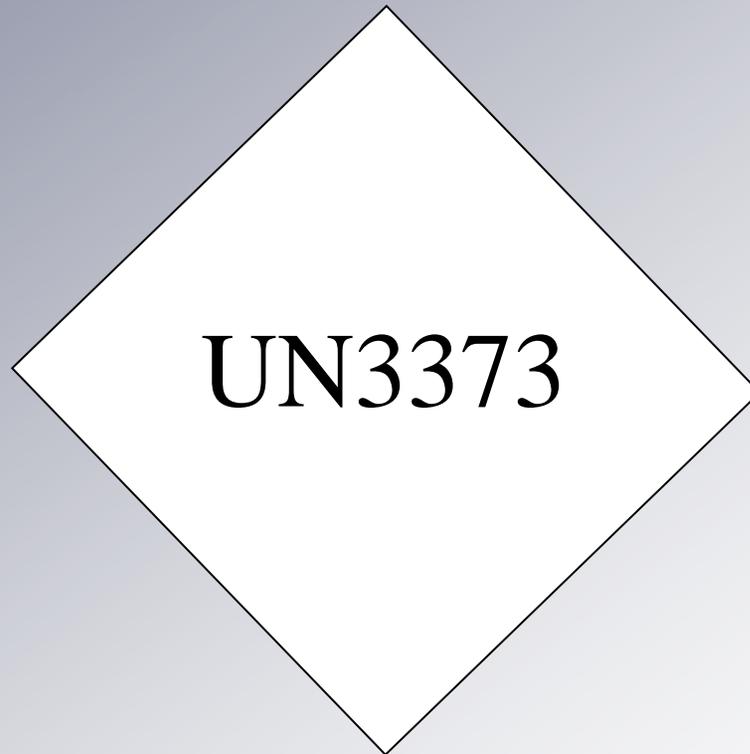
Division 6.2 Label - Cat A

- Required label for:
 - Category A Infectious Substance
 - Regulated Medical Waste(unless excepted w/Biohazard Symbol)





Biological Substance, Category B Marking

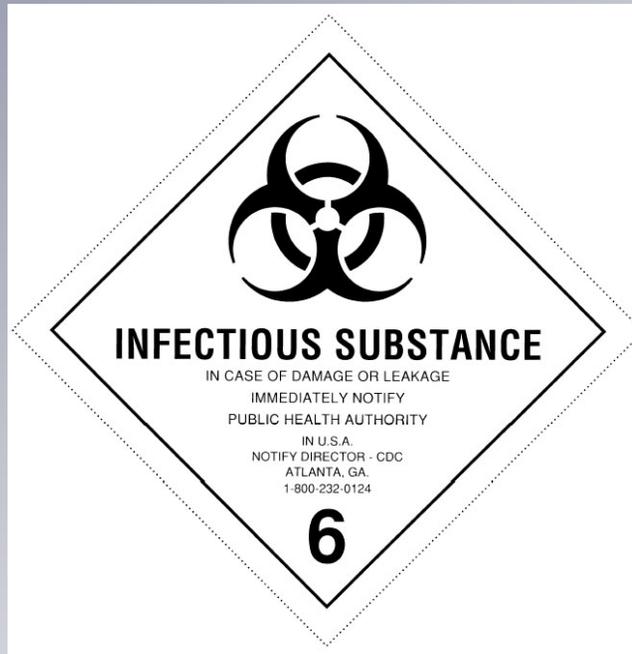




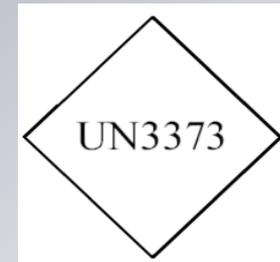
Marking and Labeling



§ 172.323(c)
& § 173.134(c)(1)(i)



§ 172.432
Label with "404" CDC number
expired 10/1/05



§ 173.199(a)(4)
Category B infectious substance



§ 172.302
Bulk Marking (can also be on
plain white placard)



Shipping Papers

- Category A
 - Identification Number
 - Proper Shipping Name
 - “Suspected Category A infectious substance”
(technical name as applicable)
 - Hazard Class/Division
 - Packing Group
 - **UN2814, Infectious Substances affecting humans,
(Suspected Category A Infectious Substance), 6.2, PG II
 - Total Quantity (Type Pkg and Qty)
 - Shipper’s Certification
 - Emergency Response Telephone Number



Shipping Papers

- Category B
 - No shipping papers required per 173.199
 - ☺ Excepted from all requirements except as listed in 173.199



Shipping Papers – Regulated Medical Waste

- Shipping description:
 - UN Identification Number
 - Proper Shipping Name
 - Hazard Class/Division
 - Packing Group
 - **UN3291, Regulated Medical Waste, 6.2, PG II
 - Total Quantity (Type Pkg & Qty)
 - Shipper's Certification
 - Emergency Response Telephone Number



Emergency Response Information

- Requirements for providing and maintaining emergency response information identified in Part 172, Subpart G
- May be on shipping paper or other document
- Exception: not required if a shipping paper is not required



Photo: Lawrence Berkeley National Lab



Division 6.2 Materials of Trade (MOTS 173.6)

- Definition
 - Hazmat on private motor carrier in direct support of principal business that is other than transportation
- Examples:
 - Home health care products, biological product or regulated medical waste



MOTS Exception

- A Division 6.2 other than Category A contained in human or animal samples transported as:
 - Research, diagnosis, investigation activities; or disease treatment or prevention, i.e.
 - Blood and its components
 - Tissue and tissue fluids
 - Body parts; or
 - Biological product (or)
 - Regulated medical waste (RMW)



MOTS Exception (cont.)

- Non-spec combination packagings with quantity limits
- Aggregate gross weight of all MOTS on motor vehicle may not exceed 200 kg (440 lbs)
- RMW: Each Inner pkg \leq 1 gal / 8.8#
Total in outer pkg \leq 35# / 4.2 gal
- 6.2 Material, other than RMW: Inner pkg \leq 17 oz/1 lbs
Total in outer pkg \leq 1 gal/8.8 lbs
- LEAK TIGHT / Pkg markings required / No shipping paper.
- Training on this section only, 173.6.



Other Requirements – Security Plan

- A security plan is required for:
 - Select agent or toxin regulated by CDC under 42 CFR part 73
 - By April 1, 2007 for select agent or toxin regulated by USDA under 9 CFR part 121
 - (Adding 7 CFR Part 331)
 - ❖ Not for RMW transportation
- The plan must include:
 - Assessment of security risks
 - Address personnel security, unauthorized access, and en-route security



Other Requirements – Training

- Federal hazardous materials transportation law 49 CFR, Part 172, Subpart H, requires training of *all* hazmat employees. Training must include:
 - General Awareness / Familiarization
 - Safety
 - Function Specific
 - Security Awareness
 - In-depth Security on Security Plan
(when applicable)
- Anyone shipping infectious substances must have “knowledge and training”



Compliance Inspections

Process: **NO NOTICE!!!!!!**

Introduction

Purpose

Packaging: Non-bulk, bulk, inner pkging/liners,

Tested packages (UN)

RMW Waste Manifests / Bills of Lading (Infectious Sub)

Training: Gen Aw/Function Spec/Sec Awareness/

Safety/Security plan (if required)

Security Plan (Select Agent Shipper per 42 CFR)

(Not required for RMW) No placards Required.

Exit Briefing: With or without violations noted.



Where to Find More Information

The screenshot shows the PHMSA Hazmat Safety Community website. The browser title is "PHMSA - Hazmat Safety Community - Microsoft Internet Explorer". The address bar shows the URL: <http://www.phmsa.dot.gov/portal/site/PHMSA/menuitem.592e107d80e9067580cd871067c277897/vgnnextoid=0f0b143389d8c010vgnvcm1000008049a8c0RCRD&vgnnextchannel=0f0b143389d8c010vgnvcm100000>

The website header includes the PHMSA logo and the text "U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration". Navigation tabs include "For the Public", "Hazmat Safety Community", "Pipeline Safety Community", "Media | Congress", and "Doing Business with PHMSA".

The main content area is titled "Hazmat Safety Community" and features a grid of links to various resources:

- About Us:** Information about PHMSA's Office of Hazardous Materials Safety.
- Electronic Services:** Available online services.
- Grants & State Programs:** Financial and technical assistance for hazardous materials emergency planning and training.
- Interpretations:** PHMSA provides review and interpretation of regulations upon request.
- Registration:** Are you required to be registered? If so, how do you go about it?
- Special Permits & Approvals:** Alternatives to HMR requirements.
- Calendar:** Planned events specific to Hazardous Materials general and specific topics.
- Enforcement:** Inspection and enforcement ensuring compliance with United States law.
- Hazardous Materials Information Center:** 1-800-HMR-4922 Mon to Fri 9 to 5 EST (202 366 4400 For Washington DC residents)
- Library:** Available files, reports, documents, and publications.
- Risk Management:** Identifying and managing risks of transportation of hazmat in commerce.
- Training & Outreach:** Training information, who needs it, and how to obtain it.
- Contact Us:** How to connect with us for more information, requests, and questions.
- FAQs:** Frequently Asked Questions about Hazardous Materials information and training.
- Incident Reporting:** Notification and reporting requirements.
- NTSB Safety Recommendations:** PHMSA is required by law to respond to recommendations issued by NTSB.
- Rules & Regulations:** What are the rules and how do they apply to me?
- Data & Statistics:** Accidents and incidents as well as average, annual, and summary statistics.
- Glossary:** Hazardous Materials terms and definitions.
- International Standards:** Forums to harmonize United States and international standards and regulations.
- Preemption Index:** Preemption is the displacing effect that Federal law has on a conflicting or inconsistent state law.
- Security:** Enhancing hazardous materials transportation safety and security.

Additional sections include:

- Home** (with "Got a Question?" link)
- About PHMSA:** Mission and Goals, About the Agency, Key Officials, Organization, Calendar.
- Promoting Safety & Security:** Regulations, Special Permits & Approvals, International Standards, Security.
- Latest News:**
 - PHMSA Press Release 07-07: DOT Grants \$12.8 Million to First Responders and Emergency Workers to Improve Hazardous Materials Planning and Training
 - PHMSA Press Release 06-07: PHMSA Bans Non-Rechargeable Lithium Battery Shipments on Passenger Aircraft
 - PHMSA Focus, Summer Edition
 - PHMSA Press Release 05-07: PHMSA signed a MOA with the National Library of Medicine (NLM), to publish PHMSA's 2008 Emergency Response Guidebook as a software application on mobile devices for use by emergency responders.
 - DOT Press Release (116-06): DOT Proposes to Require Railroads to Route Hazardous Materials Based on Range of Safety and Security Factors
- Travel Resources:** Tips on how to safely pack and transport batteries, battery-powered devices, and other personal items when traveling. Includes a "SafeTravel" logo with the text "SAFETY TIPS FOR TRAVELERS".
- What Has Changed?:** A description of significant changes made to this site recently or since the last deployment. Includes a link: "Welcome to the New Improved PHMSA Web".
- Hazardous Materials Safety Discussion**

The browser status bar at the bottom shows "Done" on the left and "Trusted sites" on the right.

<http://hazmat.dot.gov>



New

<http://hazmat.dot.gov>

Hazmat Menu

- No Placards.
- Alphabetical listing of main topics.
- Training & Outreach updated new site.

News, Calendar, and Regulatory Activity

- Program-specific topics only.
- Latest Events
 - Hazmat and PHMSA calendars and PHMSA archive.
- Rulemaking Events
 - Highlight regulatory activity.

Critical PHH Info @ Your Fingertips

- "one-stop-shop" for critical Program information.
- Glossary terms

The screenshot shows the PHMSA Hazmat Menu website. The top navigation bar includes links for Home, About PHMSA, Promoting Safety & Security, Encouraging Compliance, Supporting Community Response, PHMSA Resources, Travel Resources, Safe Travel, Hazardous Materials Safety Resources, and Freedom of Information Act. The main content area is organized into several columns of links and news items.

Callout boxes highlight the following features:

- Hazmat Menu:** A speech bubble pointing to the top navigation bar.
- Critical PHH Info @ Your Fingertips:** A speech bubble pointing to the 'Data & Statistics', 'Glossary', and 'International Standards' sections.
- Training and Outreach:** A speech bubble pointing to the 'Training & Outreach' section.
- News, Calendar, and Regulatory Activity:** A speech bubble pointing to the 'Latest Events' and 'Rulemaking Events' sections.



How You Reach Us

Hazardous Materials

INFO-LINE

1-800-HMR49-22

(1-800-467-4922)

Hours of Operation: 9 am – 5 pm ET



- Obtain answers to HMR questions
- Request copies of Federal Register, exemptions or training materials
- Report HMR violations
- Fax on Demand

E-mail: infocntr@dot.gov

