TRANSPORTING INFECTIOUS SUBSTANCES SAFELY

U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

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NOTICE

This publication was prepared as a training aid in the proper use of the Hazardous Materials Regulations (HMR) and should not be used to determine compliance with 49 CFR, Parts 100-185.

This guidance does not have the force and effect of law and is not meant to bind the regulated entities in any way.

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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 (DOT) 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 transported or offered for transportation by air, highway, rail, or water.

The Pipeline and Hazardous Materials Safety Administration (PHMSA) updated these requirements in a final rule on June 1, 2006. In that final rule, the HMR established a two-tiered classification system for infectious substances—Category A and Category B.

CLASSIFICATION SYSTEM

The classification criteria and packaging requirements for the transportation of infectious substances are consistent with international standards. The harmonization of these standards ensure an acceptable level of safety for transporting infectious substances and facilitate their domestic and international transportation.

The Category A and Category B 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 United Nations Recommendations for the Transport of Dangerous Goods (UN Recommendations), 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) International Maritime Dangerous Goods (IMDG) Code.

CATEGORY A AND CATEGORY B

DIVISION 6.2 INFECTIOUS SUBSTANCE

A Division 6.2 infectious substance is 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.

CATEGORY A

Category A classifies an infectious substance as 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, which may result 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 health risk than Category B.

PROPER SHIPPING NAMES AND IDENTIFICATION NUMBERS:

UN2814, Infectious substances, affecting humans
UN2900, Infectious substances, affecting animals

CATEGORY B

Category B classifies an infectious substance as 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 infectious substances transported for diagnostic or investigational purposes.

PROPER SHIPPING NAME AND IDENTIFICATION NUMBER:

UN3373, Biological substances, Category B

For information on Regulated Medical Waste see page 12.
Division 6.2 materials that are excepted from the regulations can be found in §173.134(b).

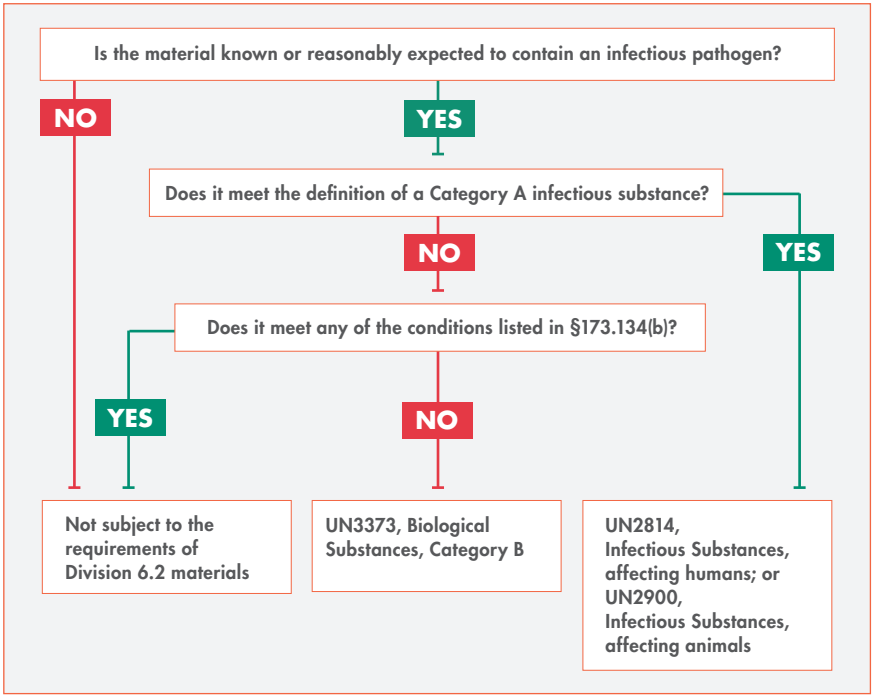
CLASSIFICATION PROCESS

SUBSTANCE FOR CLASSIFICATION

Section 173.134(b) of the HMR contains a list of scenario-based exceptions in which some materials are not subject to the requirements for Division 6.2 infectious substances. If a material meets all the conditions of any scenario, it is not regulated.

The flowchart below provides a process that can be helpful when determining if a material is infectious and/or eligible for any exceptions from the requirements. It is important to first determine if the material is known or reasonably expected to contain an infectious pathogen. If it does not contain an infectious pathogen, it is not regulated. However, a material that meets the definition of a Category A infectious substance will not be eligible for any exceptions.

Always review §173.134(b) to carefully determine if a material meets any of the conditional exceptions. The classification scenarios on the following pages provide examples of possible ways to move through a classification process.

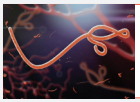


CLASSIFICATION SCENARIOS

SCENARIO 1

APPROPRIATE CLASSIFICATION

UN2814, Infectious Substances, affecting humans



A blood sample known or reasonably suspected to contain **EBOLA VIRUS**

Does it meet the definition of a Category A substance?

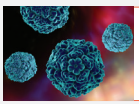
YES

UN2814, Infectious Substances, affecting humans

SCENARIO 2

APPROPRIATE CLASSIFICATION

UN2900, Infectious Substances, affecting animals



A culture of **FOOT AND MOUTH DISEASE**

Does it meet the definition of a Category A substance?

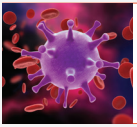
YES

UN2900, Infectious Substances, affecting animals

SCENARIO 3

APPROPRIATE CLASSIFICATION

UN3373, Biological Substances, Category B



A blood sample taken from a patient known or suspected to have a Category B pathogen, such as **HEPATITIS B or HIV**

→ Does it meet the definition of a Category A substance?

NO

Is it a patient sample transported by private or contract carrier in a motor vehicle used exclusively for these materials? (See §173.134(b)(10))

YES → Not subject to the requirements of Division 6.2 materials

NO → UN3373, Biological Substances, Category B

SCENARIO 4

APPROPRIATE CLASSIFICATION

Not subject to the Hazardous Materials Regulations

A **BLOOD SAMPLE** collected for routine testing

→ Does it meet the requirements of §173.134(b)(11)?

YES

Not subject to the requirements of Division 6.2 materials

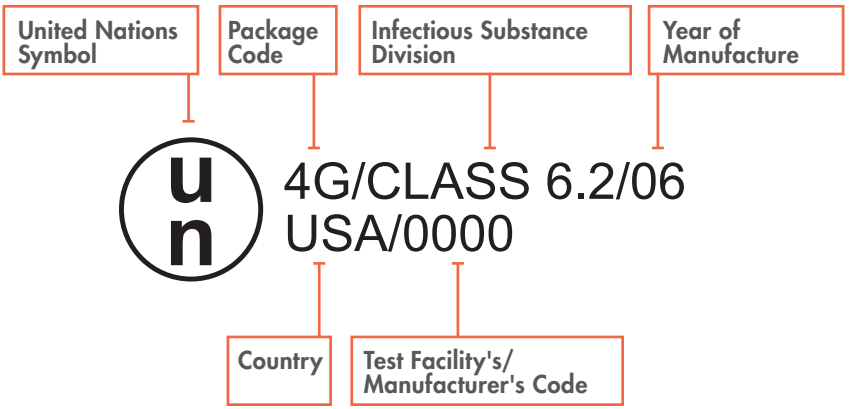
REQUIREMENTS FOR SHIPMENTS

PACKING, MARKING AND LABELING OF CATEGORY A INFECTIOUS SUBSTANCES

Requirements for packagings of Category A infectious substances are found in §173.196, and must:

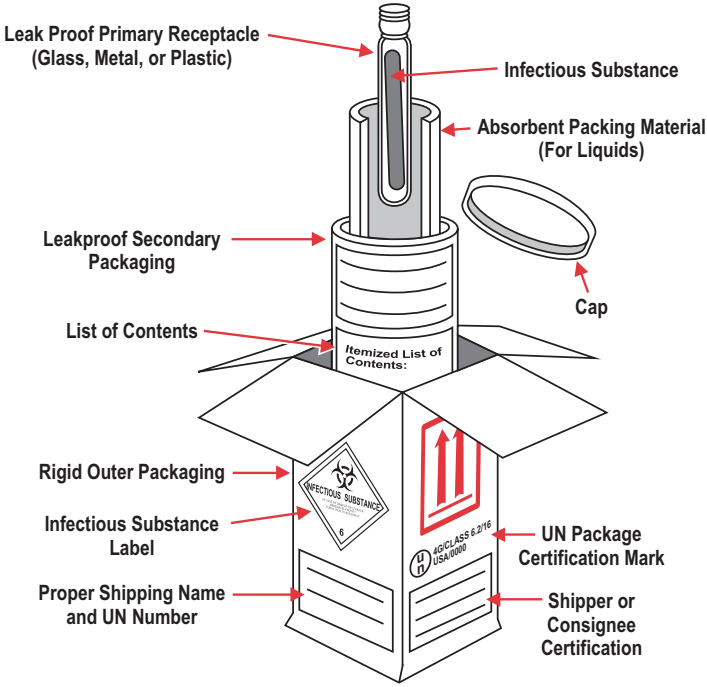
- meet the test standards of §178.609.
- be a triple packaging consisting of:
  - primary leakproof receptacle,
  - leakproof secondary packaging, and
  - rigid outer packaging.
- be marked with a UN package certification mark on the outer packaging in conformance with §178.503(f).

SAMPLE OF UN PACKAGE CERTIFICATION MARK

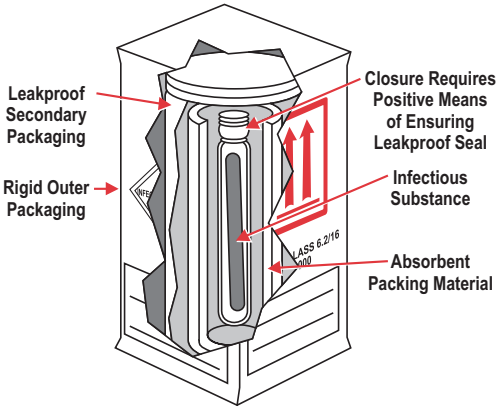


INFECTIOUS SUBSTANCE LABEL

DIAGRAM OF CATEGORY A PACKAGE



CROSS SECTION OF CLOSED PACKAGE



Notes: At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (3.9 inches). 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. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact. Follow the package manufacturer's closure instructions.

PACKING AND MARKING OF CATEGORY B INFECTIOUS SUBSTANCES

Category B infectious substances are excepted from all other requirements of the HMR when transported in accordance with the requirements of §173.199.

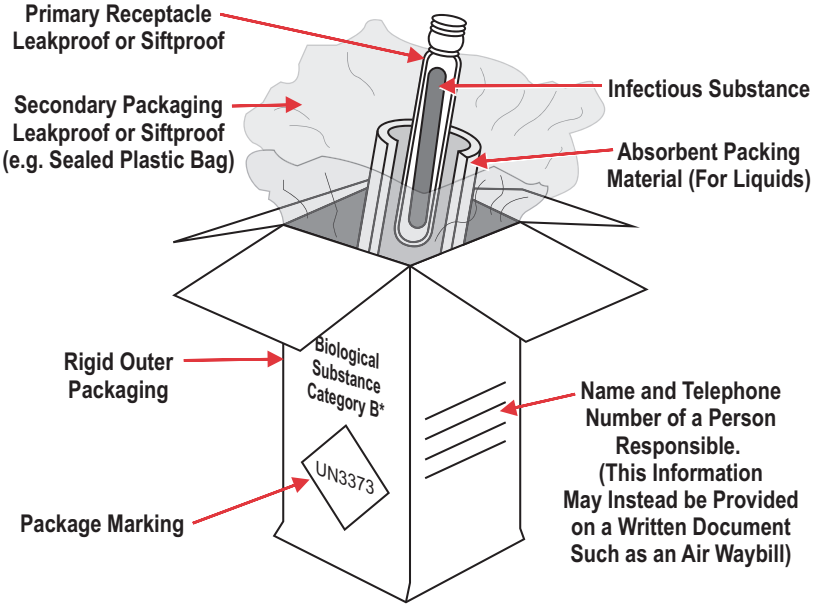
Packing of Category B infectious substances requires marking the outer package, adjacent to proper shipping name, with “Biological substances, Category B" and the UN3373 package marking.

UN3373 PACKAGE MARKING

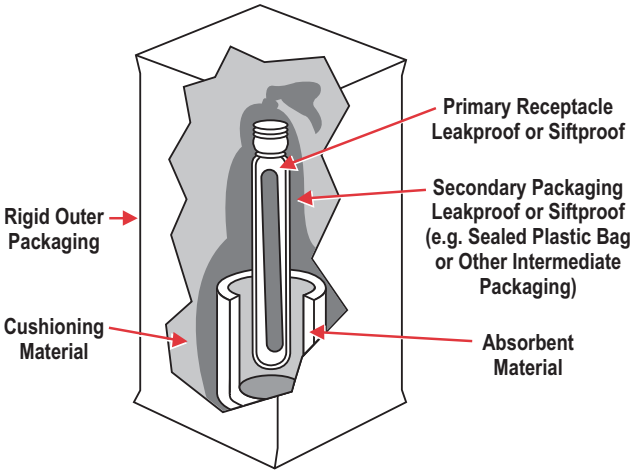
The proper shipping names “Clinical Specimen” and “Diagnostic Specimen” were previously authorized until December 31, 2006. Since January 1, 2007, only the proper shipping name “Biological substances, Category B” is authorized for use.

Section 173.199 has additional requirements and limitations for hazardous materials in other hazard classes, such as dry ice and flammable liquids. Refer to §173.199 for all requirements when shipping Category B infectious substances.

DIAGRAM OF CATEGORY B PACKAGE



CROSS SECTION OF CLOSED PACKAGE



Notes: At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (3.9 inches). 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. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact. Follow the package manufacturer's closure instructions.

REGULATED MEDICAL WASTE

PACKING, MARKING AND LABELING

Packaging requirements for regulated medical waste, including detailed inner packaging requirements for each type, can be found in §173.197 and must be marked and labeled in one of the following methods:

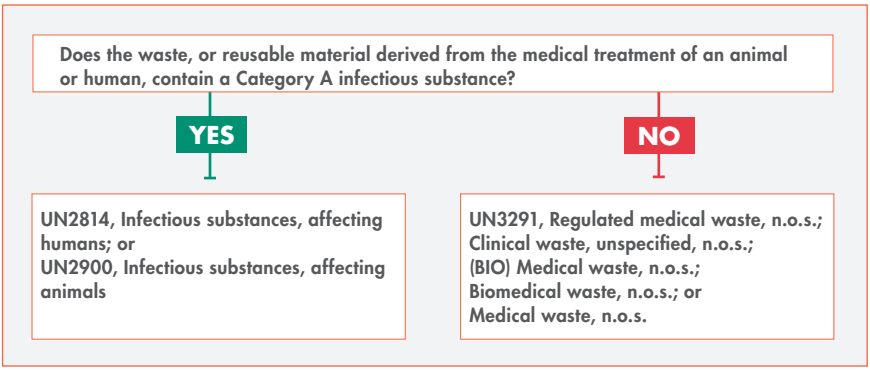
- Non-bulk Packagings (<119 gallons) – UN standard packaging conforming to the requirements of Part 178 of the HMR at the Packing Group II performance level.
    - Non-bulk packages must be marked and labeled with the UN ID number, proper shipping name, infectious substance label, and consignee's or consignor's name and address.
- Large Packagings (>119 gallons) – Constructed, tested, and marked in accordance with subparts P and Q of Part 178.
    - Large packages must be marked with the UN ID number and BIOHAZARD marking conforming to 29 CFR 1910.1030.
- Non-specification Bulk Packaging (>119 gallons) – includes wheeled carts or other bulk outer packaging.
    - Bulk packages must be marked with the UN ID number and BIOHAZARD marking conforming to 29 CFR 1910.1030.

PROPER SHIPPING NAMES AND IDENTIFICATION NUMBERS:

UN3291, Regulated medical waste, n.o.s.
Clinical waste, unspecified, n.o.s.
(BIO) Medical waste, n.o.s.
Biomedical waste, n.o.s.
Medical waste, n.o.s.

CLASSIFICATION SCENARIO

A waste material that contains a Category A infectious substance must be classified as a Category A infectious substance. The flowchart below provides a process to determine if a material is a regulated medical waste or a Category A infectious substance.



BIOHAZARD MARKING

PRIVATE OR CONTRACT CARRIERS

Regulated medical waste transported by a private or contract carrier in a motor vehicle is excepted from:

- the requirement for an "INFECTIOUS SUBSTANCE" label if the outer packaging is marked with a "BIOHAZARD" marking in accordance with 29 CFR 1910.1030;
- the specific packaging requirements of §173.197, if packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §173.24 and 29 CFR 1910.1030, provided the material does not include a waste concentrated stock culture of an infectious substance. Sharps containers must be securely closed to prevent leaks or punctures.

EXCEPTIONS

EXCEPTIONS FOR CERTAIN AIR SHIPMENTS

According to §6.3.2.3.8 of the ICAO Technical Instructions, specimen packages marked as "Exempt human specimen" or "Exempt animal specimen" **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.

MATERIALS OF TRADE

A Division 6.2 material, other than a Category A infectious substance, is eligible for the Materials of Trade exception when it complies with §173.6 and it contains 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 it is a biological product or regulated medical waste is eligible for materials of trade exceptions. Section 173.6 of the HMR describes the packaging and transport requirements for this exception. Note that there are specific quantity limitations and transport must meet the definition of material of trade in §171.8.

OTHER EXCEPTIONS

Section 173.134 identifies exceptions for infectious substances and regulated medical wastes not specifically outlined in this guide. In addition, if a DOT special permit is required (DOT-SP) you must follow all requirements described in the permit.

OTHER REQUIREMENTS

CARRIAGE BY AIRCRAFT

Section 175.630 contains special requirements for Division 6.1 (poisonous) materials and Division 6.2 (infectious substances) materials. Paragraph (c) requires the inspection of 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.

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 telephone reporting requirements and §171.16 for written report requirements.

TRAINING REQUIREMENTS

Employees involved in the packaging and transport of infectious substances are subject to the training requirements of the HMR. These requirements vary but are found in §172.704 and include:

- General awareness/familiarization training;
- Function-specific training;
- Safety training;
- Security awareness training; and
- In-depth security training (if subject to security plan requirements).

Employees involved in the packaging and transport of Category B infectious substances are required to be trained on the requirements in §173.199. Employees who perform these tasks for excepted infectious substances, such as Materials of Trade or those listed in §173.134(b) and (c), are required to be trained on the applicable requirements of each exception.

SECURITY PLANS

Persons who offer for transportation or transport select agents and toxins regulated by the Centers for Disease Control and Prevention (CDC) under 42 CFR Part 73 or the US Department of Agriculture under 9 CFR Part 121 must develop and implement security plans in accordance with §172.800 through §172.804.

EXAMPLES OF CATEGORY A: UN2814, INFECTIOUS SUBSTANCES AFFECTING HUMANS

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)

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)

EXAMPLES OF CATEGORY A: UN2900, INFECTIOUS SUBSTANCES AFFECTING ANIMALS

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)

These examples are provided as guidance only. For more information, refer to the World Health Organization (WHO) guidance on regulations for the transport of infectious substances 2019–2020 (WHO/WHE/CPI/2019.20).

DEFINITIONS

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).

REGULATED MEDICAL WASTE

Regulated medical waste or *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.

A complete list of infectious substance definitions can be found in the HMR in §173.134(a).

For additional information contact:

The Hazardous Materials Info Center

1-800-HMR-4922

(1-800-467-4922)

Email: infocntr@dot.gov

https://www.phmsa.dot.gov

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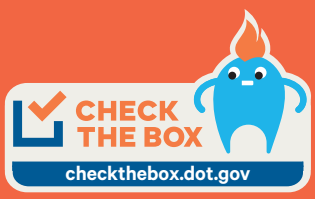

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