

346 **Toxic Substances and Infectious Substances
(Hazard Class 6)**

346.1 **Definitions**

Hazard Class 6 consists of two divisions:

- a. Division 6.1 includes toxic substances, poisons, and irritating material. Examples of Division 6.1 materials (not all of which are mailable) include bromobenzyl cyanide, methyl bromide, motor fuel anti-knock mixtures, and tear gas.
- b. Division 6.2 includes infectious substances. Examples of Division 6.2 materials include infectious substances, biological products, regulated medical waste, sharps medical waste, used health care products, and forensic materials.

346.11 **Division 6.1**

The following terms are used in the standards for Division 6.1 materials:

- a. *Toxic Substance* is a poisonous material, other than a gas, that is known to be so toxic to humans as to cause death, injury, or harm to human health if swallowed, inhaled, or brought into contact with skin.
- b. *Oral Toxicity* refers to a liquid with a lethal dose (LD₅₀) for acute oral toxicity of not more than 500 mg/kg or a solid with an LD₅₀ for acute oral toxicity of not more than 200 mg/kg that, when administered by mouth, is likely to cause death within 14 days in half of the test animals.
- c. *Dermal Toxicity* refers to a material with an LD₅₀ for acute dermal toxicity of not more than 1,000 mg/kg that, when administered by continuous contact with bare skin, is likely to cause death within 14 days in half of the test animals.
- d. *Inhalation Toxicity* applies to a dust or mist with a lethal concentration (LC₅₀) for acute inhalation toxicity of not more than 10 mg/L, or a

saturated vapor concentration in air at 68° F (20° C) of more than one-fifth of the LC₅₀ for acute toxicity on inhalation of vapors and with an LC₅₀ for acute inhalation toxicity of vapors of not more than 5,000 ml/m³ that, when administered by continuous inhalation for 1 hour, is likely to cause death within 14 days in half of the test animals.

- e. *Irritating Material* is any liquid or solid substance (such as tear gas) that gives off intense fumes and causes extreme but reversible localized irritant effects on the eyes, nose, and throat, temporarily impairing a person's ability to function.

346.12 **Division 6.2, Infectious Substances**

The following terms are used in the standards for Division 6.2 materials:

- a. *Infectious substance* means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism that can cause disease in humans or animals. Examples of pathogens include bacteria, viruses, fungi, and other infectious agents. An infectious substance must be assigned to one of the following two packaging categories:
 - (1) *Category A*: An infectious substance transported in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Category A infectious substances are nonmailable. A Category A infectious substance is assigned the identification number UN2814 or UN2900, 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.
 - (2) *Category B*: An infectious substance that does not meet the criteria for inclusion in Category A. A mailpiece known or suspected to contain a Category B infectious substance must bear the proper shipping name "Biological Substance, Category B" on the address side of the mailpiece and must be assigned to and marked with identification number UN3373 (as shown in Exhibit 346.12a2 7or, for regulated medical waste and sharps medical waste, identification number UN3291.

Exhibit 346.12a2

Mailpiece Symbol and Marking for Mailpieces Containing Biological Substance, Category B Substances



- b. *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) intended to prevent, treat, or cure a disease or condition of humans 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, mark these mailpieces with identification number UN3373 (as shown in [Exhibit 346.12a2](#)) when they contain a biological product known or reasonably expected to contain a pathogen that meets the definition of a Category B infectious substance.
- c. *Cultures* are infectious substances that result from a process by which pathogens are intentionally propagated. This definition does not include a human or animal patient specimen as defined in [346.12e](#).
- d. *Exempt human or animal specimen* means a human or animal sample (including, but not limited to, secret, excreta, blood and its components, tissue and tissue fluids, and body parts) transported for routine testing not related to the diagnosis of an infectious disease. 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. Exempt human or animal specimens are not subject to regulation as hazardous materials but must be packaged according to [346.326](#).
- e. *Patient specimen* means material that is collected directly from humans or animals and transported for purposes such as diagnosis and research. Patient specimens include excreta, secret, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (such as transwabs, culture media, and blood culture bottles).
- f. *Regulated medical waste*, for USPS purposes, means a soft waste material (other than a sharp) derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Soft medical waste includes items such as used rubber gloves, swabs, gauze, tongue depressors, and other similar material. Mark these mailpieces with identification number UN3291.
- g. *Sharps medical waste*, for USPS purposes, means a medical waste object that is capable of cutting or penetrating skin or packaging material and that is contaminated with a pathogen or may become contaminated with a pathogen derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Sharps include used medical waste such as needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. Mark these mailpieces with identification number UN3291.

- h. *Toxin* means a Division 6.1 material from a plant, animal, or bacterial source. A toxin containing an infectious substance or a toxin contained in an infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN2814, UN2900, or UN3373, as appropriate. A toxin known or suspected to contain a Category A infectious substance is nonmailable. A toxin known or suspected to contain a Category B infectious substance must be marked UN3373 and packaged under 346.321. Toxins from plant, animal, or bacterial sources that do not contain an infectious substance and are not contained in an infectious substance may be considered for classification as Division 6.1 toxic substances under 346.
- i. *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 diagnostic specimen, biological product, regulated medical waste, or sharps 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 transport.

346.2 Mailability

346.21 General

346.211 Division 6.1, Toxic Substances

The following conditions apply:

- a. *International Mail*. Division 6.1 toxic substances or poisons and irritating materials are prohibited.
- b. *Domestic Mail via Air or Surface Transportation*. A Division 6.1 toxic substance or poison that can qualify as an ORM-D material is permitted when packaged under the applicable requirements in Appendix C (Packaging Instruction 6A). Certain other poisonous materials are permitted to be mailed only between authorized parties under specific conditions as specified in 346.231b.

346.212 Division 6.2, Infectious Substances

- a. *International Mail*. Category A infectious substances are nonmailable. A material that is classified as a Category B infectious substance and that meets the definition in 346.12a2 is permitted in international mail only when sent as registered First-Class Mail International™, Express Mail International®, or Global Express Guaranteed® service; when intended for medical or veterinary use, research, or laboratory certification related to the public health; and when materials are properly prepared for mailing. The mailer must receive written approval from the office of Mailing Standards. See chapter 6 and IMM 135 for specific requirements.
- b. *Domestic Mail*. Infectious substances are permitted only when they are intended for medical or veterinary use, research, or laboratory certification related to public health, and when properly prepared for mailing to withstand shocks, pressure changes, and other conditions

incident to ordinary handling in transit. The following substances are mailable subject to the corresponding packaging requirements:

- (1) Category B infectious substance via First-Class Mail, Priority Mail, or Express Mail service.
- (2) Sharps and other mailable regulated medical waste via First-Class Mail or Priority Mail service using merchandise return service.
- (3) Used health care products via First-Class Mail, Priority Mail, or Express Mail service.
- (4) Forensic materials via First-Class Mail, Priority Mail, or Express Mail service.
- (5) Nonregulated materials via First-Class Mail, Priority Mail, Express Mail, or Package Services.
- (6) Exempt human or animal specimens via First-Class Mail, Priority Mail, Express Mail, or Package Services.

346.22 **Nonmailable Class 6 Materials**

When hazardous materials that are nonmailable under 346.2 and DMM 601.10.17 are found in the mailstream, the procedures in POM 139.117 must be followed if the materials present an immediate threat to persons or property. The procedures in POM 139.118 are followed when there is no immediate threat to persons or property.

346.221 **Division 6.1, Toxic Substances**

The following Division 6.1 materials are nonmailable:

- a. *Toxic Substances.* Any toxic material having an LD₅₀ for oral toxicity of 50 mg/kg or less is nonmailable, except when sent between authorized parties under the conditions permitted in 346.231b. Examples of nonmailable toxic materials include, but are not limited to, the following:
 - (1) Aniline oil (UN1547).
 - (2) Bromoacetone (UN1569).
 - (3) 3-Chloro-4-methylphenyl isocyanate (UN2236).
 - (4) Chloropicrin (UN1580).
 - (5) Cyanogen bromide (UN1889).
 - (6) Hexaethyl tetraphosphate, liquid or solid (UN1611).
 - (7) Hydrocyanic acid aqueous solutions (UN1613).
 - (8) Methyl bromide (UN1062).
 - (9) Methyl parathion, liquid (NA3018).
 - (10) Motor fuel antiknock mixtures (UN1649).
 - (11) Organic phosphate compound (NA1955).
 - (12) Parathion (NA2783).
 - (13) Phenylcarbylamine chloride (UN1672).
 - (14) Tetraethyl dithiopyrophosphate (UN1704).
 - (15) Tetraethyl lead, liquid (NA1649).

(16) Tetraethyl pyrophosphate, liquid (NA3018).

(17) Thiophosgene (UN2474).

b. *Irritating Materials.* All irritating materials are nonmailable. Examples include the following:

(1) Bromobenzyl cyanide (UN1694).

(2) Chloroacetophenone (UN1697).

(3) Diphenylamine chloroarsine (UN1698).

(4) Diphenylchloroarsine (UN1699).

(5) Tear gas (UN1700, NA1693, and UN1693), except for those containing oleoresin capsicum.

346.222 **Division 6.2, Infectious Substances**

The following Division 6.2 materials are nonmailable:

- a. Blood collected for the purpose of blood transfusion known or suspected to contain a Category A infectious substance.
- b. A biological product, culture, stock, or other biological specimen known or suspected to contain a Category A infectious substance. Mailpieces that exceed 4 liters (1 gallon) for liquids or 4 kg. (8.8 pounds) for solids are nonmailable.
- c. A toxin known or suspected to contain a Category A infectious substance.
- d. Sharps medical waste and regulated medical waste that contain a Category A infectious substance.
- e. Used healthcare products that contain a Category A infectious substance.

346.23 **Mailable Class 6 Materials**

In addition to the mailable types of Division 6.1 and 6.2 materials cited in 346.21, the following materials are permitted to be mailed only within the conditions noted.

346.231 **Division 6.1, Toxic Substances**

- a. *ORM-D Materials.* A Division 6.1 toxic substance that can qualify as an ORM-D material is mailable when all applicable conditions are met.
- b. *Toxic Substances with LD₅₀ Oral Toxicity of 50 mg/kg or Less.* A Division 6.1 toxic substance having an LD₅₀ for oral toxicity of greater than 5 mg/kg but less than or equal to 50 mg/kg is mailable only when sent between the following authorized parties and under the specified conditions:
 - (1) Toxic substances for scientific use (not outwardly or of their own force dangerous or injurious to life, health, or property) may be sent only between manufacturers, dealers, bona fide research or experimental scientific laboratories, and employees of federal, state, or local governments who have official use for such poisons and are designated by the agency head to receive or send such poisons.
 - (2) Poisonous drugs and medicines may be sent only from the manufacturer or dealer of the drugs and medicines to licensed

physicians, surgeons, dentists, pharmacists, druggists, cosmetologists, barbers, and veterinarians (18 U.S.C. 1716). In limited circumstances, when the mailing is initiated by a drug manufacturer or the manufacturer's registered agent, customers may return prescription drugs to the manufacturer or its registered agent as indicated in [473.6](#).

346.232 Other Nonregulated Toxic Materials

Liquids and solids such as pesticides, insecticides, and herbicides that are not regulated as hazardous materials under 49 CFR are mailable subject to Postal Service quantity restrictions that are based on the toxicity of the material.

- a. *Liquids*. Restrictions are as follows, subject to the general packaging requirements in DMM 601.1–8:
 - (1) A nonregulated toxic liquid having an LD₅₀ of 50 to 500 mg/kg is permitted up to 16 fluid ounces per mailpiece.
 - (2) A nonregulated toxic liquid having an LD₅₀ of 500 to 2,500 mg/kg is permitted up to 32 fluid ounces in a glass primary receptacle, or up to 1 gallon in a non-glass primary receptacle. Only one primary receptacle is permitted per mailpiece.
 - (3) A nonregulated toxic liquid having an LD₅₀ of 2,500 to 5,000 mg/kg is permitted up to 1 gallon in a glass primary receptacle, or up to 2 gallons in a non-glass primary receptacle. Only one primary receptacle is permitted per mailpiece.
 - (4) A nonregulated toxic liquid having an LD₅₀ of greater than 5,000 mg/kg is permitted with no quantity restriction.
 - (5) External markings specifying the contents and shipping papers are not required for nonregulated toxic liquids.
- b. *Solids*. Restrictions are as follows:
 - (1) A nonregulated toxic solid for which an LD₅₀ rate equivalent to liquids can be established is mailable under the same quantity restrictions for Division 6.1 toxic substances specified in Packaging Instruction 6A in Appendix C and DMM 601.10.16.
 - (2) Packaging requirements for a nonregulated toxic solid are the same as those for Division 6.1 toxic substance (see Packaging Instruction 6A in Appendix C), except that up to 5 pounds may be contained in a single primary receptacle. Only one primary receptacle is permitted per mailpiece.
 - (3) External markings specifying the contents and shipping papers are not required for nonregulated toxic solids.

346.233 Division 6.2, Infectious Substances

Infectious substances, biological products, cultures and stocks, exempt human or animal specimens, patient specimens, regulated medical waste, sharps medical waste, toxins, and used health care products are permitted to be mailed within specific quantity limits and packaging conditions specified in [346.3](#) and DMM 601.10.17.

346.234 Nonregulated Materials

The following materials are not subject to regulation as Division 6.2 hazardous materials and are mailable when the packaging requirements specified in Packaging Instructions 6D in Appendix C and DMM 610.10.17.8 are met:

- a. A biological product, including an experimental or investigational product or component of a product, subject to federal approval, permit, review, or licensing requirements, such as those required by the Food and Drug Administration of the U.S. Department of Health and Human Services or the U.S. Department of Agriculture. A biological product known or suspected to contain a Category B infectious substance must be marked UN3373 (as shown in Exhibit 346.12a2) and packaged under 346.321. A biological product known or suspected to contain a Category A infectious substance is nonmailable.
- b. Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; plasma; plasma derivatives; blood components; tissues or organs intended for use in transplant operations; and human cell, tissue, and cellular and tissue-based products regulated under the Public Health Service Act (42 U.S.C. 264-272) or the Food, Drug, and Cosmetic Act (21 U.S.C. 332 et seq.).
- c. Blood, blood plasma, and blood components collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except when the person collecting the blood has reason to believe it contains a Category B infectious substance, in which case the test sample must be shipped as a Category B infectious substance. Materials known or suspected to contain a Category A infectious substance are nonmailable.
- d. Dried blood spots, collected by applying a drop of blood to absorbent material, or dried specimens for fecal occult blood detection. (These materials are not classified as exempt human or animal specimens.)
- e. Forensic material containing a biological material, such as tissue, body fluid, excreta, or secreta, not expected to contain a Category A or Category B infectious substance and transported on behalf of a federal, state, local, or Indian tribal government agency. A forensic material known or suspected to contain a Category B infectious substance must be shipped as a Category B infectious substance. A forensic material known or suspected to contain a Category A infectious substance is nonmailable.

346.3 Packaging, Marking, Labeling, and Documentation**346.31 Division 6.1, Toxic Substances**

Mailable toxic substances must be prepared as follows:

- a. *ORM-D Materials*. The applicable requirements specified in 346.211 and 346.231 must be met. Packaging Instruction 6A in Appendix C must be followed. Each mailpiece must be plainly and durably marked on the address side with "ORM-D" or "ORM-D AIR," as applicable, immediately following or below the proper shipping name (Consumer

Commodity). For air transportation, each mailpiece must bear a shipper's declaration for dangerous goods (i.e., shipping paper). Mailable material sent via surface transportation must be marked on the address side as "Surface Mail Only" or "Surface Only."

- b. *Toxic Substances with LD₅₀ Oral Toxicity of 50 mg/kg or Less.* The applicable requirements specified in 346.211 and 346.231 must be met. Packaging Instruction 6B in Appendix C must be followed. Each mailpiece must be plainly and durably marked on the address side with the proper shipping name and UN number of the material (unless exempted by DMM 601.11.11.2). Mailable materials sent via surface transportation must be marked on the address side as "Surface Mail Only" or "Surface Only." For air or surface transportation, each mailpiece must bear a shipping paper.

346.32 **Division 6.2, Infectious Substances**

The proper packaging, marking, labeling, and documentation for mailable Division 6.2 materials are described in the following sections.

346.321 **Category B Infectious Substances**

Note: See Packaging Instructions 6C in Appendix C and DMM 601.10.17.4.

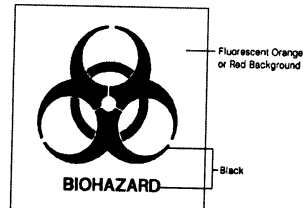
A material that is classified as a Category B infectious substance and that meets the definition in 346.12a2 must be triple-packaged, meeting the packaging requirements in 49 CFR 173.199, and sent with First-Class Mail, Priority Mail, or Express Mail service. Each primary receptacle containing a liquid must be leakproof and surrounded by absorbent material sufficient to protect the primary receptacle and absorb the total amount of liquid should the primary receptacle leak or break. Each primary receptacle containing a solid must be siftproof. Secondary containers for liquids must be leakproof. Secondary containers for solids must be siftproof. The primary and secondary packaging must be enclosed in a rigid outer shipping container. A single primary receptacle must not contain more than 1 liter (34 ounces) of a liquid specimen or 4 kg (8.8 pounds) of a solid specimen. Two or more primary receptacles whose combined volume does not exceed 4 liters (1 gallon) for liquids or 4 kg (8.8 pounds) for solids may be enclosed in a single secondary container. In addition:

- a. The secondary container must be marked with the international biohazard symbol shown in Exhibit 346.321.
- b. The primary receptacle or secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) in the range of -40°F to 130°F (-40°C to 55°C).
- c. All mailpieces sent under 346.322 must be marked on the address side with the shipping name "Biological Substance, Category B" and "UN3373" (as shown in Exhibit 346.12a2) and as outlined in 49 CFR 173.199(a)(5). Regulated medical waste and sharps medical waste as defined in 346.12f and 346.12g must be marked UN3291. See 346.322.
- d. Orientation arrows are not required on these mailpieces but may be used.

- e. The outer packaging must show the name and telephone number of a person who is knowledgeable about the material shipped and has comprehensive emergency response and incident mitigation information, or of someone who has immediate access to the person with such knowledge and information.

Exhibit 346.321

International Biohazard Symbol



USPS Packaging Instruction 6C

Category B Infectious Substances

DMM Reference 601.10.7.4

Infectious substance means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism that can cause disease in humans or animals. Examples of pathogens include bacteria, viruses, fungi, and other infectious agents. An infectious substance must be assigned to one of the following two packaging categories:

- Category A: Category A infectious substances are not mailable.
- Category B: An infectious substance that does not meet the criteria for inclusion in Category A. A mailpiece known or suspected to contain a Category B infectious substance is mailable as described in [346](#) and DMM 601.10.17.

Proper Shipping Name and ID Number

- Biological substance, Category B, UN3373.

Mailability

- International Mail: Mailable when they meet the definition in [346.12a2](#) and IMM 135 when written approval has been granted by the manager of Mailing Standards. Category B infectious substances may be sent with registered First-Class Mail International, Express Mail International, or Global Express Guaranteed service.
- Domestic Mail: Mailable only when they are intended for medical or veterinary use, research, or laboratory certification related to the public health, and when such materials are properly prepared for mailing to withstand shocks, pressure changes, and other conditions related to ordinary handling in transit. Unless otherwise noted, all mailable Division 6.2 materials must meet the mail preparation requirements for air transportation and sent with First-Class Mail, Priority Mail, or Express Mail service.

Required Packaging

- Must be triple-packaged, meeting the packaging requirements in 49 CFR 173.199, and surrounded by absorbent material sufficient to protect the primary receptacle and absorb the total amount of liquid should the primary receptacle leak or break.

Primary Receptacle (Container)

- Each primary receptacle containing a liquid must be leakproof. Each primary receptacle containing a solid must be siftproof.
- A single primary receptacle must not contain more than 1 liter (34 ounces) of a liquid specimen or 4 kg (8.8 pounds) of a solid specimen.
- Two or more primary receptacles whose combined volume does not exceed 4 liters (1 gallon) for liquids or 4 kg (8.8 pounds) for solids may be enclosed in a single secondary container.

Cushioning and Absorbent Material

- The space between the primary receptacle(s) and the secondary container at the top, bottom, and sides must contain enough material to absorb the entire contents of the primary receptacle(s) in case of breakage or leakage.
- Either the primary receptacle or the secondary container must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 0.95 bar, 14 psi (95 kPa), and temperatures in the range of -40° F to 131° F (-40° C to 55° C).

Secondary Container

- Secondary containers for liquids must be leakproof. Secondary containers for solids must be siftproof. The secondary packaging must be constructed of a durable material and have a secure sealing method.
- If the primary receptacle does not meet the pressure requirements listed above, then the secondary container must be designed to meet those requirements.
- The secondary container must be marked with the international biohazard symbol shown in [Exhibit 346.321](#).

Outer Shipping Container

- The address side of the outer shipping container must be marked with the proper shipping name "Biological Substance, Category B" and UN3373. See [Exhibit 346.12a2](#).
- The address side of the outer shipping container must be marked with the name and telephone number of a person who is knowledgeable about the material shipped and has comprehensive emergency response and incident mitigation information, or someone who has immediate access to the person with such knowledge and information.
- The primary and secondary packaging must be enclosed in a rigid outer shipping container. The primary receptacle(s) and the secondary container must be enclosed in a strong outer packaging constructed of fiberboard or other equivalent material.
- At least one surface of the outer shipping container must have a minimum dimension of 3.9 inches by 3.9 inches (100 mm by 100 mm) as required by 49 CFR 173.199.

Markings

As required by 49 CFR 173.199:

- Each mailpiece (outer shipping container) must be marked with the proper shipping name “Biological Substance, Category B” and have the diamond marking indicating UN3373 (see Exhibit 346.12a2).
- The address side of the outer shipping container must be marked with name and telephone number of a person who is knowledgeable about the material shipped and has comprehensive emergency response and incident mitigation information, or someone who has immediate access to the person with such knowledge and information.
- Orientation arrows are not required on these mailpieces but may be used.

International Mail

- Substances identified in IMM 135.11b *must* be sent *only* by authorized laboratories to their foreign counterparts in those countries that have indicated a willingness to accept them.

Note: Countries distinguish between infectious and noninfectious (nonregulated) biological substances and may prohibit one or the other or both. See “Prohibitions” in the Individual Country Listings.

- Infectious biological substances can be sent to or received by *only* the following types of institutions:
 - a. Laboratories of local, state, and federal government agencies.
 - b. Laboratories of federally licensed manufacturers of biological products derived from bacteria and viruses.
 - c. Laboratories affiliated with or operated by hospitals, universities, research facilities, and other teaching institutions.
 - d. Private laboratories licensed, certified, recognized, or approved by a public authority.