§ 173.132 Class 6, Division 6.1—Definitions

(a) For the purpose of this subchapter, poisonous material (Division 6.1) means a material, other than a gas, which is known to be so toxic to humans as to afford a hazard to health during transportation, or which, in the absence of adequate data on human toxicity:

(1) Is presumed to be toxic to humans because it falls within any one of the following categories when tested on laboratory animals (whenever possible, animal test data that has been reported in the chemical literature should be used):

(i) Oral Toxicity. A liquid or solid with an LD$_{50}$ for acute oral toxicity of not more than 300 mg/kg.

(ii) Dermal Toxicity. A material with an LD$_{50}$ for acute dermal toxicity of not more than 1000 mg/kg.

(iii) Inhalation Toxicity. (A) A dust or mist with an LC$_{50}$ for acute toxicity on inhalation of not more than 4 mg/L; or

(B) A material with a saturated vapor concentration in air at 20°C (68°F) greater than or equal to one-fifth of the LC$_{50}$ for acute toxicity on inhalation of vapors and with an LC$_{50}$ for acute toxicity on inhalation of vapors of not more than 5000 mL/m$^3$; or

(2) Is an irritating material, with properties similar to tear gas, which causes extreme irritation, especially in confined spaces.

(b) For the purposes of this subchapter—

(1) LD$_{50}$ (median lethal dose) for acute oral toxicity is the statistically derived single dose of a substance that can be expected to cause death within 14 days in 50% of young adult albino rats when administered by the oral route. The LD$_{50}$ value is expressed in terms of mass of test substance per mass of test animal (mg/kg).

(2) LD$_{50}$ for acute dermal toxicity means that dose of the material which, administered by continuous contact for 24 hours with the shaved intact skin (avoiding abrading) of an albino rabbit, causes death within 14 days in half of the animals tested. The number of animals tested must be sufficient to give statistically valid results and be in conformity with good pharmacological practices. The result is expressed in mg/kg body mass.

(3) LC$_{50}$ for acute toxicity on inhalation means that concentration of vapor, mist, or dust which, administered by continuous inhalation for one hour to both male and female young adult albino rats, causes death within 14 days in half of the animals tested. If the material is administered to the animals as a dust or mist, more than 90 percent of the particles available for inhalation in the test must have a diameter of 10 microns or less if it is reasonably foreseeable that such concentrations could be encountered by a human during transport. The result is expressed in mg/L of air for dusts and mists or in mL/m$^3$ of air (parts per million) for vapors. See §173.133(b) for LC$_{50}$ determination for mixtures and for limit tests.

(i) When provisions of this subchapter require the use of the LC$_{50}$ for acute toxicity on inhalation of dusts and mists based on a one-hour exposure and such data is not available, the LC$_{50}$ for acute toxicity on
inhalation based on a four-hour exposure may be multiplied by four and the product substituted for the one-hour LC$_{50}$ for acute toxicity on inhalation.

(ii) When the provisions of this subchapter require the use of the LC$_{50}$ for acute toxicity on inhalation of vapors based on a one-hour exposure and such data is not available, the LC$_{50}$ for acute toxicity on inhalation based on a four-hour exposure may be multiplied by two and the product substituted for the one-hour LC$_{50}$ for acute toxicity on inhalation.

(iii) A solid substance should be tested if at least 10 percent of its total mass is likely to be dust in a respirable range, e.g. the aerodynamic diameter of that particle-fraction is 10 microns or less. A liquid substance should be tested if a mist is likely to be generated in a leakage of the transport containment. In carrying out the test both for solid and liquid substances, more than 90% (by mass) of a specimen prepared for inhalation toxicity testing must be in the respirable range as defined in this paragraph (b)(3)(iii).

(c) For purposes of classifying and assigning packing groups to mixtures possessing oral or dermal toxicity hazards according to the criteria in §173.133(a)(1), it is necessary to determine the acute LD$_{50}$ of the mixture. If a mixture contains more than one active constituent, one of the following methods may be used to determine the oral or dermal LD$_{50}$ of the mixture:

(1) Obtain reliable acute oral and dermal toxicity data on the actual mixture to be transported;

(2) If reliable, accurate data is not available, classify the formulation according to the most hazardous constituent of the mixture as if that constituent were present in the same concentration as the total concentration of all active constituents; or

(3) If reliable, accurate data is not available, apply the formula:

$$\frac{C_A}{T_A} + \frac{C_B}{T_B} + \frac{C_Z}{T_Z} = \frac{100}{T_M}$$

where:

C = the % concentration of constituent A, B ... Z in the mixture;

T = the oral LD$_{50}$ values of constituent A, B ... Z;

TM = the oral LD$_{50}$ value of the mixture.

Note to formula in paragraph (c)(3): This formula also may be used for dermal toxicities provided that this information is available on the same species for all constituents. The use of this formula does not take into account any potentiation or protective phenomena.

(d) The foregoing categories shall not apply if the Associate Administrator has determined that the physical characteristics of the material or its probable hazards to humans as shown by documented experience indicate that the material will not cause serious sickness or death.

§ 173.133 Assignment of packing group and hazard zones for Division 6.1 materials

(a) The packing group of Division 6.1 materials shall be as assigned in column 5 of the §172.101 table. When the §172.101 table provides more than one packing group or hazard zone for a hazardous material, the packing group and hazard zone shall be determined by applying the following criteria:

(1) The packing group assignment for routes of administration other than inhalation of vapors shall be in accordance with the following table:

<table>
<thead>
<tr>
<th>Packing Group</th>
<th>Oral Toxicity LD₅₀ (mg/kg)</th>
<th>Dermal Toxicity LD₅₀ (mg/kg)</th>
<th>Inhalation toxicity by dusts and mists LC₅₀ (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>≤ 5.0</td>
<td>≤ 50</td>
<td>≤ 0.2</td>
</tr>
<tr>
<td>II</td>
<td>&gt; 5.0 and ≤ 50</td>
<td>&gt; 50 and ≤ 200</td>
<td>&gt; 0.2 and ≤ 2.0</td>
</tr>
<tr>
<td>III</td>
<td>&gt; 50 and ≤ 300</td>
<td>&gt; 200 and ≤ 1000</td>
<td>&gt; 2.0 and ≤ 4.0</td>
</tr>
</tbody>
</table>

(2)(i) The packing group and hazard zone assignments for liquids (see §173.115(c) of this subpart for gases) based on inhalation of vapors shall be in accordance with the following table:

<table>
<thead>
<tr>
<th>Packing Group</th>
<th>Vapor concentration and toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (hazard Zone A)</td>
<td>V ≥ 500 LC₅₀ and LC₅₀ ≤ 200 mL/m³</td>
</tr>
<tr>
<td>I (hazard Zone B)</td>
<td>V ≥ 10 LC₅₀; LC₅₀ ≤ 1000 mL/m³; and the criteria for Packing Group I, Hazard Zone A are not met.</td>
</tr>
<tr>
<td>II</td>
<td>V ≥ LC₅₀; LC₅₀ ≤ 3000 mL/m³; and the criteria for Packing Group I, are not met.</td>
</tr>
<tr>
<td>III</td>
<td>V ≥ 0.2 LC₅₀; LC₅₀ ≤ 5000 mL/m³; and the criteria for Packing Groups I and II, are not met.</td>
</tr>
</tbody>
</table>

Note 1: V is the saturated vapor concentration in air of the material in mL/m³ at 20 °C and standard atmospheric pressure.

Note 2: A liquid in Division 6.1 meeting criteria for Packing Group I, Hazard Zones A or B stated in paragraph (a)(2) of this section is a material poisonous by inhalation subject to the additional hazard communication requirements in §§172.203(m), 172.313 and table 1 of §172.504(e) of this subchapter.
(ii) These criteria are represented graphically in Figure 1:

Figure 1
Inhalation Toxicity: Packing Group and Hazard Zone Borderlines

(3) When the packing group determined by applying these criteria is different for two or more (oral, dermal or inhalation) routes of administration, the packing group assigned to the material shall be that indicated for the highest degree of toxicity for any of the routes of administration.

(4) Notwithstanding the provisions of this paragraph, the packing group and hazard zone of a tear gas substance is as assigned in column 5 of the §172.101 table.

(b) The packing group and hazard zone for Division 6.1 mixtures that are poisonous (toxic) by inhalation may be determined by one of the following methods:

(1) Where LC50 data is available on each of the poisonous (toxic) substances comprising the mixture—

(i) The LC50 of the mixture is estimated using the formula:

\[
LC_{50}(\text{mixture}) = \frac{1}{\sum_{i=1}^{n} \frac{f_i}{LC_{50i}}}
\]

where

\( f_i \) = mole fraction of the \( i \)th component substance of the liquid.

\( LC_{50i} \) = mean lethal concentration of the \( i \)th component substance in \( mL/m^3 \)

(ii) The volatility of each component substance is estimated using the formula:

\[
V_i = P_i \times 10^6 \times \frac{101.3}{mL/m^3}
\]
where:

Pi = partial pressure of the \( i \)th component substance in kPa at 20 °C and one atmospheric pressure. Pi may be calculated according to Raoult's Law using appropriate activity coefficients. Where activity coefficients are not available, the coefficient may be assumed to be 1.0.

(iii) The ratio of the volatility to the LC50 is calculated using the formula:

\[
R = \sum_{i=1}^{n} \frac{V_i}{LC_{50i}}
\]

(iv) Using the calculated values LC50 (mixture) and R, the packing group for the mixture is determined as follows:

<table>
<thead>
<tr>
<th>Packing Group (hazard zone)</th>
<th>Ratio of volatility and LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (hazard Zone A)</td>
<td>( R \geq 500 ) LC50 (mixture) ( \leq 200 \text{ mL/m}^3 )</td>
</tr>
<tr>
<td>I (hazard Zone B)</td>
<td>( R \geq 10 ) LC50 (mixture) ( \leq 1000 \text{ mL/m}^3 ); and the criteria for Packing Group I, Hazard Zone A are not met.</td>
</tr>
<tr>
<td>II</td>
<td>( R \geq 1 ) LC50 (mixture) ( \leq 3000 \text{ mL/m}^3 ); and the criteria for Packing Group I, Hazard Zones A and B are not met.</td>
</tr>
<tr>
<td>III</td>
<td>( R \geq 1/5 ) and LC50 (mixture) ( \leq 5000 \text{ mL/m}^3 ); and the criteria for Packing Groups I, Hazard Zones A and B, and Packing Group II are not met.</td>
</tr>
</tbody>
</table>

(2) In the absence of LC50 data on the poisonous (toxic) constituent substances, the mixture may be assigned a packing group and hazard zone based on the following simplified threshold toxicity tests. When these threshold tests are used, the most restrictive packing group and hazard zone must be determined and used for the transportation of the mixture.

(i) A mixture is assigned to Packing Group I, Hazard Zone A only if both the following criteria are met:

(A) A sample of the liquid mixture is vaporized and diluted with air to create a test atmosphere of 200 mL/m\(^3\) vaporized mixture in air. Ten albino rats (five male and five female) are exposed to the test atmosphere as determined by an analytical method appropriate for the material being classified for one hour and observed for fourteen days. If five or more of the animals die within the fourteen-day observation period, the mixture is presumed to have an LC50 equal to or less than 200 mL/m\(^3\).

(B) A sample of the vapor in equilibrium with the liquid mixture is diluted with 499 equal volumes of air to form a test atmosphere. Ten albino rats (five male and five female) are exposed to the test atmosphere for one hour and observed for fourteen days. If five or more of the animals die within the fourteen-day observation period, the mixture is presumed to have volatility equal to or greater than 500 times the mixture LC50.

(ii) A mixture is assigned to Packing Group I, Hazard Zone B only if both the following criteria are met, and the mixture does not meet the criteria for Packing Group I, Hazard Zone A:

(A) A sample of the liquid mixture is vaporized and diluted with air to create a test atmosphere of 1000 mL/m\(^3\) vaporized mixture in air. Ten albino rats (five male and five female) are exposed to the test atmosphere for one hour and observed for fourteen days. If five or more of the animals die within the
fourteen-day observation period, the mixture is presumed to have an LC50 equal to or less than 1000 mL/m³.

(B) A sample of the vapor in equilibrium with the liquid mixture is used to form a test atmosphere. Ten albino rats (five male and five female) are exposed to the test atmosphere for one hour and observed for fourteen days. If five or more of the animals die within the fourteen-day observation period, the mixture is presumed to have volatility equal to or greater than the mixture LC50.

(iv) A mixture is assigned to Packing Group III only if both the following criteria are met, and the mixture does not meet the criteria for Packing Groups I (Hazard Zones A or B) or Packing Group II (Hazard Zone C):

(A) A sample of the liquid mixture is vaporized and diluted with air to create a test atmosphere of 5000 mL/m³ vaporized mixture in air. Ten albino rats (five male and five female) are exposed to the test atmosphere for one hour and observed for fourteen days. If five or more of the animals die within the fourteen-day observation period, the mixture is presumed to have an LC50 equal to or less than 5000 mL/m³.

(B) The vapor pressure of the liquid mixture is measured and if the vapor concentration is equal to or greater than 1000 mL/m³, the mixture is presumed to have a volatility equal to or greater than 1/5 the mixture LC50.


§ 173.134 Class 6, Division 6.2—Definitions and exceptions

(a) Definitions and classification criteria. For the purposes of this subchapter, the following definitions and classification criteria apply to Division 6.2 materials.

(1) Division 6.2 (Infectious substance) means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals. An infectious substance must be assigned the identification number UN 2814, UN 2900, UN 3373, or UN 3291 as appropriate, and must be assigned to one of the following categories:

(i) 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. A Category A infectious substance must be assigned to identification number UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 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.

(ii) Category B: An infectious substance that is 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. A Category B infectious substance must be described as “Biological substance, Category
B" and assigned identification number UN 3373. This does not include regulated medical waste, which must be assigned identification number UN 3291.

(2) **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) applicable to the prevention, treatment, or cure of a disease or condition of human beings 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, a biological product known or reasonably expected to contain a pathogen that meets the definition of a Category A or B infectious substance must be assigned the identification number UN 2814, UN 2900, or UN 3373, as appropriate.

(3) **Culture** means an infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimen as defined in paragraph (a)(4) of this section.

(4) **Patient specimen** means human or animal material 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).

(5) **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, as appropriate.

(6) **Sharps** means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. Sharps includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.

(7) **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 UN 2814 or UN 2900, as appropriate.

(8) **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 patient specimen, biological product, or regulated medical 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 transportation.

(b) **Exceptions.** The following are not subject to the requirements of this subchapter as Division 6.2 materials:

(1) A material that does not contain an infectious substance or that is unlikely to cause disease in humans or animals.

(2) Non-infectious biological materials from humans, animals, or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA or other non-infectious genetic elements.

(3) A material containing micro-organisms that are non-pathogenic to humans or animals.

(4) A material containing pathogens that have been neutralized or inactivated such that they no longer pose a health risk.

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(5) A material with a low probability of containing an infectious substance, or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include: Foodstuffs; environmental samples, such as water or a sample of dust or mold; and substances that have been treated so that the pathogens have been neutralized or deactivated, such as a material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.

(6) 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.

(7) 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, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act (42 U.S.C. 264–272) and/or the Food, Drug, and Cosmetic Act (21 U.S.C. 332 et seq.).

(8) 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 where the person collecting the blood has reason to believe it contains an infectious substance, in which case the test sample must be shipped as a Category A or Category B infectious substance in accordance with §173.196 or §173.199, as appropriate.

(9) Dried blood spots or specimens for fecal occult blood detection placed on absorbent filter paper or other material.

(10) A Division 6.2 material, other than a Category A infectious substance, contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or a biological product, when such materials are transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination. If the human or animal sample or biological product meets the definition of regulated medical waste in paragraph (a)(5) of this section, it must be offered for transportation and transported in conformance with the appropriate requirements for regulated medical waste.

(11) A human or animal sample (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability the sample is infectious.

(12) Laundry and medical equipment and used health care products, as follows:

(i) Laundry or medical equipment conforming to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030. This exception includes medical equipment intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. This exception does not apply to medical equipment being transported for disposal.

(ii) Used health care products not conforming to the requirements in 29 CFR 1910.1030 and being returned to the manufacturer or the manufacturer's designee are excepted from the requirements of
this subchapter when offered for transportation or transported in accordance with this paragraph (b)(12). For purposes of this paragraph, a health care product is used when it has been removed from its original packaging. Used health care products contaminated with or suspected of contamination with a Category A infectious substance may not be transported under the provisions of this paragraph.

(A) Each used health care product must be drained of free liquid to the extent practicable and placed in a watertight primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. For a used health care product capable of cutting or penetrating skin or packaging material, the primary container must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).

(B) Each primary container must be placed inside a watertight secondary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. The secondary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).

(C) The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. An itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outside packaging.

(D) Each person who offers or transports a used health care product under the provisions of this paragraph must know about the requirements of this paragraph.

(13) Any waste or recyclable material, other than regulated medical waste, including—

(i) Household waste as defined in §171.8, when transported in accordance with applicable state, local, or tribal requirements.

(ii) Sanitary waste or sewage;

(iii) Sewage sludge or compost;

(iv) Animal waste generated in animal husbandry or food production; or

(v) Medical waste generated from households and transported in accordance with applicable state, local, or tribal requirements.

(14) Corpses, remains, and anatomical parts intended for interment, cremation, or medical research at a college, hospital, or laboratory.

(15) Forensic material transported on behalf of a U.S. Government, state, local or Indian tribal government agency, except that—

(i) Forensic material known or suspected to contain a Category B infectious substance must be shipped in a packaging conforming to the provisions of §173.24.

(ii) Forensic material known or suspected to contain a Category A infectious substance or an infectious substance listed as a select agent in 42 CFR Part 73 must be transported in packaging capable of meeting the test standards in §178.609 of this subchapter. The secondary packaging must be marked with a BIOHAZARD symbol conforming to specifications in 29 CFR 1910.1030(g)(1)(i). An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
(16) Agricultural products and food as defined in the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 332 et seq.).

(c) Exceptions for regulated medical waste. The following provisions apply to the transportation of regulated medical waste:

(1) A regulated medical waste transported by a private or contract carrier is excepted from—

(i) The requirement for an “INFECTIOUS SUBSTANCE” label if the outer packaging is marked with a “BIOHAZARD” marking in accordance with 29 CFR 1910.1030; and

(ii) 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 173.24a and packaging requirements specified in 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.

(2) A waste stock or culture of a Category B infectious substance may be offered for transportation and transported as a regulated medical waste when it is packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030 and transported by a private or contract carrier in a vehicle used exclusively to transport regulated medical waste. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination. Sharps containers must be securely closed to prevent leaks or punctures.

(d) If an item listed in paragraph (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of this subchapter.