mixture is presumed to have an LC_{50} equal to or less than 1000 mL/m³.

(B) A sample of the vapor in equilibrium with the liquid mixture is diluted with 9 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 a volatility equal to or greater than 10 times the mixture LC_{50}.

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

(A) A sample of the liquid mixture is vaporized and diluted with air to create a test atmosphere of 3000 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 LC_{50} equal to or less than 3000 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 a volatility equal to or greater than the mixture LC_{50}.

(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 LC_{50} 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 ⅕ the mixture LC_{50}.

(e) *Transitional provisions.* The Division 6.1 classification criteria in effect on December 31, 2006, may continue to be used until January 1, 2012.

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended at 56 FR 66268–66270, Dec. 20, 1991; 57 FR 45461–45463, Oct. 1, 1992; Amdt. 173–234, 58 FR 51532, Oct. 1, 1993; Amdt. 173–138, 59 FR 49133, Sept. 26, 1994; Amdt. 173–255, 61 FR 50626, Sept. 26, 1996; 66 FR 45183, 45380, Aug. 28, 2001; 66 FR 49556, Sept. 28, 2001; 69 FR 54046, Sept. 7, 2004; 71 FR 54395, Sept. 14, 2006; 71 FR 78631, Dec. 29, 2006; 74 FR 53188, Oct. 16, 2009; 76 FR 43529, July 20, 2011]

§ 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.

(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.

(c) *Transitional provisions.* The criteria for packing group assignments in effect on December 31, 2006, may continue to be used until January 1, 2012.

[67 FR 53138, Aug. 14, 2002, as amended at 68 FR 57632, Oct. 6, 2003; 70 FR 56098, Sept. 23, 2005; 71 FR 32258, June 2, 2006; 71 FR 78631, Dec. 29, 2006; 72 FR 55692, Oct. 1, 2007; 73 FR 4718, Jan. 28, 2008; 74 FR 2257, Jan. 14, 2009; 76 FR 43530, July 20, 2011]

§ 173.136 Class 8—Definitions.

(a) For the purpose of this subchapter, ''corrosive material'' (Class 8) means a liquid or solid that causes full thickness destruction of human skin at the site of contact within a specified period of time. A liquid, or a solid which may become liquid during transportation, that has a severe corrosion rate on steel or aluminum based on the criteria in § 173.137(c)(2) is also a corrosive material. Whenever practical, *in vitro* test methods authorized in § 173.137 of this part or historical data authorized in paragraph (c) of this section should be used to determine whether a material is corrosive.

(b) If human experience or other data indicate that the hazard of a material is greater or less than indicated by the results of the tests specified in paragraph (a) of this section, PHMSA may revise its classification or make the determination that the material is not subject to the requirements of this subchapter.

(c) Skin corrosion test data produced no later than September 30, 1995, using the procedures of part 173, appendix A, in effect on September 30, 1995 (see 49 CFR part 173, appendix A, revised as of October 1, 1994) for appropriate exposure times may be used for classification and assignment of packing group for Class 8 materials corrosive to skin.

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended at 56 FR 66270, Dec. 20, 1991; Amdt. 173–234, 58 FR 51532, Oct. 1, 1993; Amdt. 173–241, 59 FR 67508, Dec. 29, 1994; Amdt. 173–261, 62 FR 24732, May 6, 1997; 69 FR 76155, Dec. 20, 2004; 71 FR 78631, Dec. 29, 2006; 76 FR 3372, Jan. 19, 2011]

§ 173.137 Class 8—Assignment of packing group.

The packing group of a Class 8 material is indicated in Column 5 of the § 172.101 Table. When the § 172.101 Table provides more than one packing group for a Class 8 material, the packing group must be determined using data obtained from tests conducted in accordance with the OECD Guideline for the Testing of Chemicals, Number 435, ''*In Vitro* Membrane Barrier Test Method for Skin Corrosion'' (IBR, *see* § 171.7 of this subchapter) or Number 404, ''Acute Dermal Irritation/Corrosion'' (IBR, *see* § 171.7 of this subchapter). A material that is determined not to be corrosive in accordance with OECD Guideline for the Testing of Chemicals, Number 430, ''*In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)'' (IBR, *see* § 171.7 of this subchapter) or Number 431, ''*In Vitro* Skin Corrosion: Human Skin Model Test'' (IBR, *see* § 171.7 of this subchapter) may be considered not to be corrosive to human skin for the purposes of this subchapter without further testing. However, a material determined to be corrosive in accordance with Number