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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 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 LC₅₀.

(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 LC₅₀ 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 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.

[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]

§ 173.134 Class 6, Division 6.2—Definitions, exceptions and packing group assignments.

(a) *Definitions.* For the purposes of this subchapter, the categories of materials that constitute Division 6.2 are defined as follows:

(1) An *infectious substance* means a viable microorganism, or its toxin, that causes or may cause disease in humans or animals, and includes those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services and any other agent that causes or may cause severe, disabling or fatal disease. The terms *infectious substance* and *etiologic agent* are synonymous.

(2) A *diagnostic specimen* means any human or animal material including, but not limited to, excreta, secretions, blood, blood components, tissue, and tissue fluids, being shipped for purposes of diagnosis.

(3) A *biological product* means a material that is prepared and manufactured in accordance with the provisions of 9 CFR part 102 (Licenses for biological products), 9 CFR part 103 (Experimental products, distribution, and evaluation of biological products prior to licensing), 9 CFR part 104 (Permits for biological products), 21 CFR part 312 (Investigational new drug application), or 21 CFR parts 600 to 680 (Biologics).

(4) A *regulated medical waste* means a waste or reusable material, other than a culture or stock of an infectious substance, that contains an infectious substance and is generated in—

(i) The diagnosis, treatment or immunization of human beings or animals;

(ii) Research pertaining to the diagnosis, treatment or immunization of human beings or animals; or

(iii) The production or testing of biological products.

(b) *Exceptions.* (1) The following are not subject to any requirements of this subchapter if the items as packaged do not contain any material otherwise subject to the requirements of this subchapter:

(i) Biological products;

(ii) Diagnostic specimens;

(iii) Laundry or medical equipment that conforms to 29 CFR 1910.1030 of the regulations of the Occupational Safety and Health Administration of the Department of Labor;

(iv) A material, including waste, that previously contained an infectious substance and has been treated by steam sterilization, chemical disinfection, or other appropriate method, so that it no longer poses the hazard of an infectious substance;

(v) Any waste material, including garbage, trash and sanitary waste in septic tanks, derived from households, including but not limited to single and multiple residences, hotels and motels;

(vi) Corpses, remains and anatomical parts that are intended for ceremonial interment or cremation; and

(vii) Animal waste generated in animal husbandry or food production.

(2) A hazardous waste is not subject to regulation as a regulated medical waste.

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

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

(ii) For other than a waste culture or stock of an infectious substance, the specific packaging requirements of §173.197, if packaged in a rigid non-bulk packaging conforming to—

(A) The general packaging requirements of §§173.24 and 173.24a; and

(B) Packaging requirements specified in 29 CFR 1910.1030.

(4) A waste culture or stock of infectious substances may be offered for

transportation and transported as a regulated medical waste when the culture or stock—

(i) Conforms to Biosafety Level 1, 2 or 3, as defined in HHS Publication No. (CDC) 93-8395, *Biosafety in Microbiological and Biomedical Laboratories*, 3rd Edition, May 1993, Section II;

(ii) Is packaged in accordance with requirements specified in §173.197; and

(iii) Is transported by a private or contract carrier using a vehicle dedicated to the transportation of medical waste.

(c) *Assignment of packing groups and applicable packaging sections.* (1) Division 6.2 materials, other than regulated medical waste, are not assigned a packing group. Packaging requirements for these materials are prescribed in §173.196.

(2) Except as otherwise provided, regulated medical waste is assigned to Packing Group II and must be packaged as specified in §173.197.

[Amdt. 173-247, 60 FR 48787, Sept. 20, 1995, as amended by Amdt. 173-255, 61 FR 50626, Sept. 26, 1996]

§ 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 that has a severe corrosion rate on steel or aluminum based on the criteria in §173.137(c)(2) is also a corrosive material.

(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, RSPA 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