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 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}.

[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, secreta, 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]

EFFECTIVE DATE NOTE: At 67 FR 53138, Aug. 14, 2002, § 173.134 was revised, effective Oct. 1, 2002. At 67 FR 54967, Aug. 27, 2002, the effective date was corrected to Feb. 14, 2003. For the convenience of the user, the revised text is set forth as follows:

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

(a) *Definitions and classification criteria.* For purposes of this subchapter, the following definitions and classification criteria apply:

(1) *Division 6.2 (infectious substance)* means a material known to contain or suspected of containing a pathogen. A pathogen is a virus or micro-organism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals. A Division 6.2 material must be assigned to a risk group in accordance with this paragraph (a). Assignment to a risk group is based on known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal. Infectious substances are subject to applicable requirements in 42 CFR Part 72—Interstate Shipment of Etiologic Agents.

(2) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure

of diseases in humans or animals. A *biological product* includes a material manufactured and distributed in accordance with one of the following provisions: 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); 21 CFR part 314 (Applications for FDA Approval to Market a New Drug); 21 CFR parts 600 to 680 (Biologics); or 21 CFR part 812 (Investigational Device Exemptions). A *biological product* known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate, unless otherwise excepted.

(3) *Cultures and stocks* means a material prepared and maintained for growth and storage and containing a Risk Group 2, 3 or 4 infectious substance.

(4) *Diagnostic specimen* means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals. A *diagnostic specimen* is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 pathogen, in which case it must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal.

(5) *Regulated medical waste* means a waste or reusable material known to contain or suspected of containing an infectious substance in Risk Group 2 or 3 and generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment or immunization of human beings or animals; or the production or testing of biological products. *Regulated medical waste* containing an infectious substance in Risk Group 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

(6) *Risk group* means a ranking of a micro-organism's ability to cause injury through disease. A *risk group* is defined by criteria developed by the World Health Organization (WHO) based on the severity of the disease caused by the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. There is no relationship between a *risk group* and a packing group. The criteria for each *risk group* according to the level of risk are as follows:

RISK GROUP TABLE

Risk group	Pathogen	Risk to individuals	Risk to the community
4	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.	High	High.
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	High	Low.
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	Moderate	Low.
1	A micro-organism that is unlikely to cause human or animal disease. A material containing only such micro-organisms is not subject to the requirements of this subchapter.	None or very low	None or very low.

(7) *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.

(8) *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.

(9) *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, 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 biological product known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen.

(2) A diagnostic specimen known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen, or a diagnostic specimen in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs.

(3) A biological product, including an experimental product or component of a product, subject to Federal approval, permit, or licensing requirements, such as those required by the Food and Drug Administration of the Department of Health and Human Services or the U.S. Department of Agriculture.

(4) Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; 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 and/or the Food, Drug, and Cosmetic Act.

(5) Blood 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 in accordance with §173.199.

(6) A diagnostic specimen or biological product when transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products. 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 a diagnostic specimen 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.

(7) 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.

(8) A material, including waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.

(9) A living person.

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

(i) Garbage and trash derived from hotels, motels, and households, including but not limited to single and multiple residences;

(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.

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

(12) 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 Risk Group 2 or 3 infectious substance must be shipped in a packaging conforming to the provisions of §173.24.

(ii) Forensic material known or suspected to contain a Risk Group 4 infectious substance or an infectious substance listed as a select agent in 42 CFR Part 72 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.

(13) Environmental microbiological samples, such as a sample of dust from a ventilation system or mold from a wallboard, collected to evaluate occupational and residential exposure risks.

(14) Agricultural products and food as defined in the Federal Food, Drug, and Cosmetics Act.

(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) For other than a waste culture or stock of an infectious substance, the specific packaging requirements of this section 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.

(2) A waste culture or stock of a Risk Group 2 or 3 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 using a vehicle dedicated to the transportation of 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.

(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.

§ 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 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]

§ 173.137 Class 8—Assignment of packing group.

The packing group of 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 1992 OECD Guideline for Testing of Chemicals, Number 404 ''Acute Dermal Irritation/Corrosion'' as follows:

(a) *Packing Group I.* Materials that cause full thickness destruction of intact skin tissue within an observation period of up to 60 minutes starting after the exposure time of three minutes or less.

(b) *Packing Group II.* Materials other than those meeting Packing Group I criteria that cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after the exposure time of more than three minutes but not more than 60 minutes.

(c) *Packing Group III.* Materials, other than those meeting Packing Group I or II criteria—

(1) That cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or

(2) That do not cause full thickness destruction of intact skin tissue but exhibit a corrosion rate on steel or aluminum surfaces exceeding 6.25 mm (0.25 inch) a year at a test temperature of 55 °C (130 °F). For the purpose of testing steel P3 (ISO 9328–1) or a similar type, and for testing aluminum, non-clad