(6) *Type F.* Organic peroxide type F is an organic peroxide which will not detonate in a cavitated state, does not deflagrate, shows only a low, or no, effect if heated when confined, and has low, or no, explosive power.

(7) *Type G.* Organic peroxide type G is an organic peroxide which will not detonate in a cavitated state, will not deflagrate at all, shows no effect when heated under confinement, and shows no explosive power. A type G organic peroxide is not subject to the requirements of this subchapter for organic peroxides of Division 5.2 provided that it is thermally stable (self-accelerating decomposition temperature is 50 °C (122 °F) or higher for a 50 kg (110 pounds) package). An organic peroxide meeting all characteristics of type G except thermal stability and requiring temperature control is classed as a type F, temperature control organic peroxide.

(c) *Procedure for assigning an organic peroxide to a generic type.* An organic peroxide shall be assigned to a generic type based on—

(1) Its physical state (i.e., liquid or solid), in accordance with the definitions for liquid and solid in §171.8 of this subchapter;

(2) A determination as to its control temperature and emergency temperature, if any, under the provisions of §173.21(f); and

(3) Performance of the organic peroxide under the test procedures specified in the UN Manual of Tests and Criteria, and the provisions of paragraph (d) of this section.

(d) *Approvals.* (1) An organic peroxide must be approved, in writing, by the Associate Administrator for Hazardous Materials Safety, before being offered for transportation or transported, including assignment of a generic type and shipping description, except for—

(i) An organic peroxide which is identified by technical name in the Organic Peroxides Table in §173.225(b);

(ii) A mixture of organic peroxides prepared according to §173.225(c)(5); or

(iii) An organic peroxide which may be shipped as a sample under the provisions of §173.225(c).

(2) A person applying for an approval must submit all relevant data concerning physical state, temperature controls, and tests results or an approval issued for the organic peroxide by the competent authority of a foreign government.

(e) *Tests.* The generic type for an organic peroxide shall be determined using the testing protocol from Figure 20.1(a) (Classification and Flow Chart Scheme for Organic Peroxides) from the UN Manual of Tests and Criteria.

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended at 56 FR 66268, 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]

§173.129 Class 5, Division 5.2—Assignment of packing group.

All Division 5.2 materials are assigned to Packing Group II in column 5 of the §172.101 table.

§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 with an LD_{50} for acute oral toxicity of not more than 500 mg/kg or a solid with an LD_{50} for acute oral toxicity of not more than 200 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 10 mg/L; or

(B) A material with a saturated vapor concentration in air at 20 °C (68 °F) of more than 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} for acute oral toxicity means that dose of the material administered to both male and female young adult albino rats which causes death within 14 days in half 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.

(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;

T_M = 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 for Hazardous Materials Safety 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.

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended at 56 FR 66268, Dec. 20, 1991; Amdt. 173–234, 58 FR 51532, Oct. 1, 1993; Amdt. 173–261, 62 FR 24732, May 6, 1997; 62 FR 45702, August 28, 1997]

§ 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:

Packing Group	Oral toxicity LD_{50} (mg/kg)	Dermal toxicity LD_{50} (mg/kg)	Inhalation toxicity by dusts and mists LC_{50} (mg/L)
I	≤ 5	≤ 40	≤ 0.5
II	> 5, ≤ 50	> 40, ≤ 200	> 0.5, ≤2
III	solids: > 50, ≤ 200; liquids: > 50, ≤ 500	> 200, ≤ 1000	> 2, ≤ 10

(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:

Packing Group	Vapor concentration and toxicity
I (Hazard Zone A)	V ≥ 500 LC_{50} and LC_{50} ≤ 200 mL/M³.
I (Hazard Zone B)	V ≥ 10 LC_{50}; LC_{50} ≤ 1000 mL/m³; and the criteria for Packing Group I, Hazard Zone A are not met.
II	V ≥ LC_{50}; LC_{50} ≤ 3000 mL/m³; and the criteria for Packing Group I, are not met.
III	V ≥ .2 LC_{50}; LC_{50} ≤ 5000 mL/m³; and the criteria for Packing Groups I and II, are not met.

Note 1: V is the saturated vapor concentration in air of the material in mL/m³ at 20C° 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)(3), 172.313 and table 1 of § 172.504(e) of this subchapter.

(ii) These criteria are represented graphically in Figure 1:

(d) The foregoing categories shall not apply if the Associate Administrator for Hazardous Materials Safety 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.

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended at 56 FR 66268, Dec. 20, 1991; Amdt. 173–234, 58 FR 51532, Oct. 1, 1993; Amdt. 173–261, 62 FR 24732, May 6, 1997; 62 FR 45702, August 28, 1997]

§ 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:

Packing Group	Oral toxicity LD_{50} (mg/kg)	Dermal toxicity LD_{50} (mg/kg)	Inhalation toxicity by dusts and mists LC_{50} (mg/L)
I	≤ 5	≤ 40	≤ 0.5
II	> 5, ≤ 50	> 40, ≤ 200	> 0.5, ≤2
III	solids: > 50, ≤ 200; liquids: > 50, ≤ 500	> 200, ≤ 1000	> 2, ≤ 10

(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:

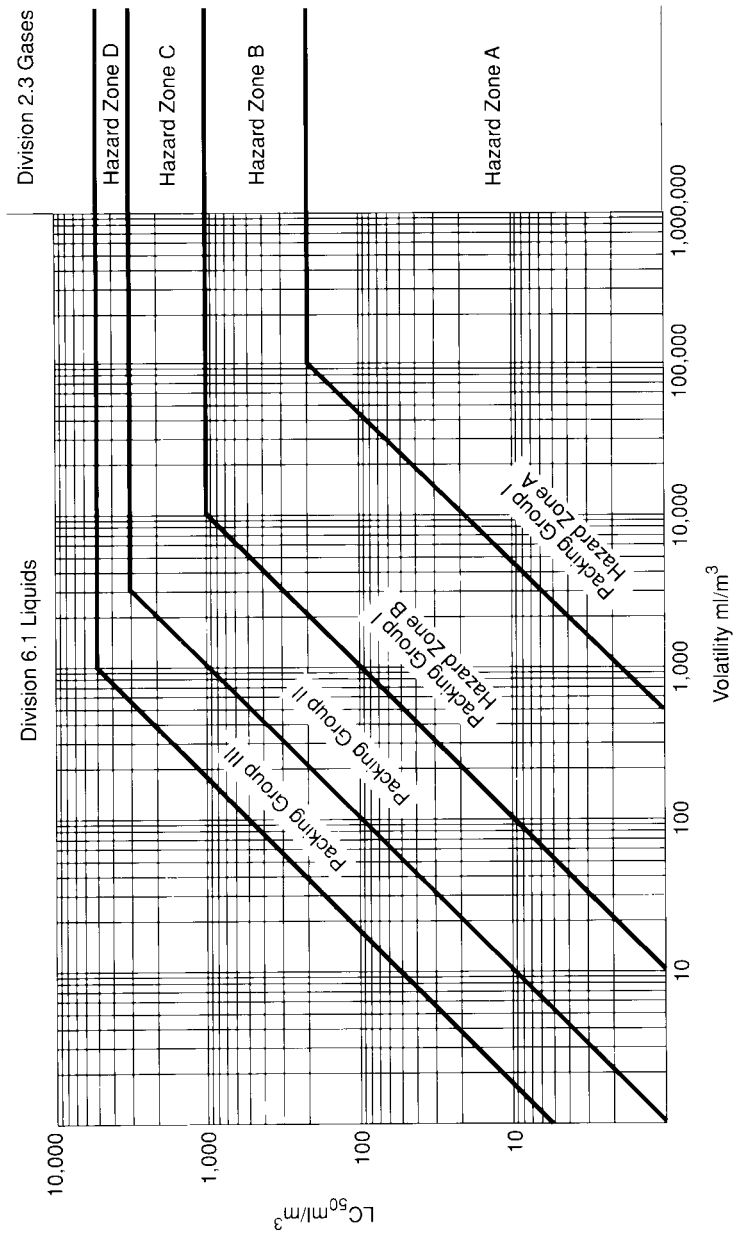
Packing Group	Vapor concentration and toxicity
I (Hazard Zone A)	V ≥ 500 LC_{50} and LC_{50} ≤ 200 mL/M³.
I (Hazard Zone B)	V ≥ 10 LC_{50}; LC_{50} ≤ 1000 mL/m³; and the criteria for Packing Group I, Hazard Zone A are not met.
II	V ≥ LC_{50}; LC_{50} ≤ 3000 mL/m³; and the criteria for Packing Group I, are not met.
III	V ≥ .2 LC_{50}; LC_{50} ≤ 5000 mL/m³; and the criteria for Packing Groups I and II, are not met.

Note 1: V is the saturated vapor concentration in air of the material in mL/m³ at 20C° 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)(3), 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 LC_{50} data is available on each of the poisonous (toxic) substances comprising the mixture—

(i) The LC_{50} of the mixture is estimated using the formula:

$$LC50\ (mixture) = \frac{1}{\sum_{i=1}^{n} \frac{f_i}{LC50_i}}$$

where

f_i = mole fraction of the i^{th} component substance of the liquid.

$LC50_i$ = 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:

$$V_i = P_i \times \frac{10^6}{101.3}\ ml/m^3$$

where:

P_i = 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 LC_{50} is calculated using the formula:

$$R = \sum_{i=1}^{n} \frac{V_i}{L_{c50i}}$$

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

Packaging group (hazard zone)	Ratio of volatility and LC_{50}
I (Hazard Zone A) ..	R ≥ 500 and LC_{50} (mixture) ≤ 200 ml/m³.
I (Hazard Zone B) ..	R ≥ 10 and LC_{50} (mixture) ≤ 1000 ml/m³; and the criteria for Packing Group I, Hazard Zone A, are not met.
II	R ≥ 1 and LC_{50} (mixture) ≤ 3000 ml/m³; and the criteria for Packing Group I, Hazard Zones A and B are not met.
III	R ≥ 1/5 and LC_{50} (mixture) ≤ 5000 ml/m³; and the criteria for Packing Group I, Hazard Zones A and B, and Packing Group II are not met.

(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 a 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 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 ⅕ the mixture LC50.

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§ 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;