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.

[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; 65 FR 58629, Sept. 29, 2000; 66 FR 45379, 45382, Aug. 28, 2001]

§ 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:

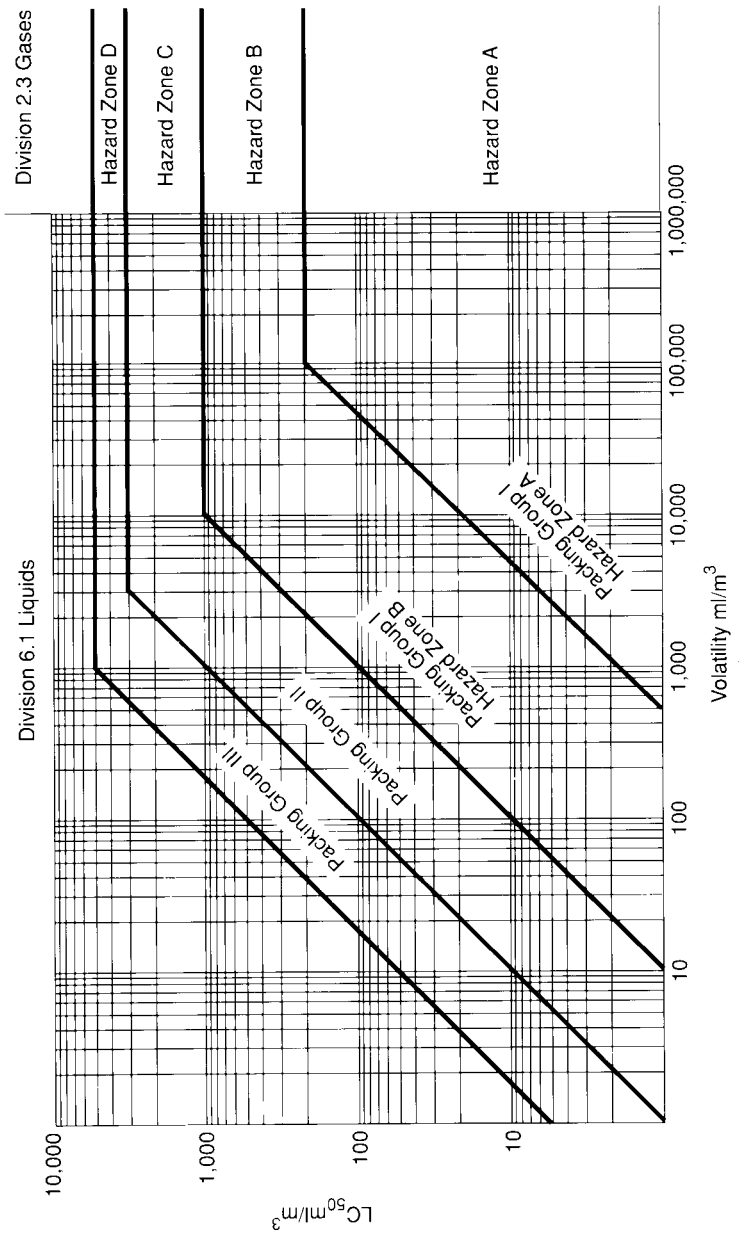
Packing Group	Vapor concentration and toxicity
I (Hazard Zone A)	V ≥ 500 LC_{50} and LC_{50} ≤ 200 mL/M³.
I (Hazard Zone B)	V ≥ 10 LC_{50}; LC_{50} ≤ 1000 mL/m³; and the criteria for Packing Group I, Hazard Zone A are not met.
II	V ≥ LC_{50}; LC_{50} ≤ 3000 mL/m³; and the criteria for Packing Group I,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

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:

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

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 LC_{50} (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 LC_{50} 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 LC_{50} 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 LC_{50}.

(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 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;