§ 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 or solid with an $LD_{50}$for acute oral toxicity of not more than 300 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 4 mg/L; or

(B) A material with a saturated vapor concentration in air at 20 °C (68 °F) greater than or equal to 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}(median lethal dose) for acute oral toxicity is the statistically derived single dose of a substance that can be expected to cause death within 14 days in 50% of young adult albino rats when administered by the oral route. The LD_{50}value is expressed in terms of mass of test substance per mass of test animal (mg/kg).

(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 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.

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