

(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 (IBR, see § 171.7 of this subchapter), and the provisions of paragraph (d) of this section.

(d) *Approvals.* (1) An organic peroxide must be approved, in writing, by the Associate Administrator, 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(c);

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

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

(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 (IBR, see § 171.7 of this subchapter).

[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; 65 FR 58629, Sept. 29, 2000; 66 FR 8647, Feb. 1, 2001; 66 FR 45379, Aug. 28, 2001; 68 FR 75744, Dec. 31, 2003; 69 FR 76155, Dec. 20, 2004]

§ 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 hu-

mans 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 LD₅₀ for acute oral toxicity of not more than 500 mg/kg or a solid with an LD₅₀ for acute oral toxicity of not more than 200 mg/kg.

(ii) *Dermal Toxicity.* A material with an LD₅₀ for acute dermal toxicity of not more than 1000 mg/kg.

(iii) *Inhalation Toxicity.* (A) A dust or mist with an LC₅₀ 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) greater than or equal to one-fifth of the LC₅₀ for acute toxicity on inhalation of vapors and with an LC₅₀ for acute toxicity on inhalation of vapors of not more than 5000 mL/mm³; 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) LD₅₀ (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 LD₅₀ value is expressed in terms of mass of test substance per mass of test animal (mg/kg).

(2) LD₅₀ 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) LC₅₀ for acute toxicity on inhalation means that concentration of

§ 173.133

49 CFR Ch. I (10–1–06 Edition)

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/m³ of air (parts per million) for vapors. See § 173.133(b) for LC₅₀ determination for mixtures and for limit tests.

(i) When provisions of this subchapter require the use of the LC₅₀ for acute toxicity on inhalation of dusts and mists based on a one-hour exposure and such data is not available, the LC₅₀ for acute toxicity on inhalation based on a four-hour exposure may be multiplied by four and the product substituted for the one-hour LC₅₀ for acute toxicity on inhalation.

(ii) When the provisions of this subchapter require the use of the LC₅₀ for acute toxicity on inhalation of vapors based on a one-hour exposure and such data is not available, the LC₅₀ for acute toxicity on inhalation based on a four-hour exposure may be multiplied by two and the product substituted for the one-hour LC₅₀ 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 LD₅₀ of the mixture. If a mixture contains more than one ac-

tive constituent, one of the following methods may be used to determine the oral or dermal LD₅₀ 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 LD₅₀ values of constituent A, B ... Z;

T_M = the oral LD₅₀ 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.

[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; 69 FR 76155, Dec. 20, 2004]

§ 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: