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; 69 FR 76155, Dec. 20, 2004; 71 FR 78631, Dec. 29, 2006; 76 FR 3372, Jan. 19, 2011; 85 FR 27880, May 11, 2020]

#### §173.137 Class 8—Assignment of packing group.

The packing group of a 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 OECD Guidelines for the Testing of Chemicals, Test No. 435, "In Vitro Membrane Barrier Test Method for Skin Corrosion" (IBR, see §171.7 of this subchapter) or Test No. 404, "Acute Dermal Irritation/Corrosion" (IBR, see §171.7 of this subchapter). A material that is determined not to be corrosive in accordance with OECD Guideline for the Testing of Chemicals, Test No. 430, "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" (IBR, see §171.7 of this subchapter) or Test No. 431, "In Vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method" (IBR, see §171.7 of this subchapter) may be considered not to be corrosive to human skin for the purposes of this subchapter without further testing. However, a material determined to be corrosive in accordance with Test No. 430 must be further tested using Test No. 435 or Test No. 404. If the in vitro test results indicate that the substance or mixture is corrosive, but the test method does not clearly distinguish between assignment of packing groups II and III, the material may be considered to be in packing group II without further testing. The packing group assignment

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using data obtained from tests conducted in accordance with OECD Guideline Test No. 404 or Test No. 435 must be as follows:

(a) *Packing Group I.* Materials that cause irreversible damage to 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 irreversible damage to 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 irreversible damage to 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 irreversible damage to intact skin tissue but exhibit a corrosion on either steel or aluminum surfaces exceeding 6.25 mm (0.25 inch) a year at a test temperature of 55 °C (130 °F) when tested on both materials. The corrosion may be determined in accordance with the UN Manual of Tests and Criteria (IBR, see §171.7 of this subchapter) or other equivalent test methods.

(d) Alternative packing group assignment methods for mixtures. For mixtures it is necessary to obtain or derive information that allows the criteria to be applied to the mixture for the purpose of classification and assignment of packing groups. The approach to classification and assignment of packing groups is tiered, and is dependent upon the amount of information available for the mixture itself, for similar mixtures and/or for its ingredients. The flow chart in Figure 1 to paragraph (d) outlines the process to be followed:

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(1) Bridging principles. Where a mixture has not been tested to determine its skin corrosion potential, but there is sufficient data on both the individual ingredients and similar tested mixtures to adequately classify and assign a packing group for the mixture, this data will be used in accordance with the following bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

(i) Dilution. If a tested mixture is diluted with a diluent, which does not meet the criteria for Class 8 and does not affect the packing group of other ingredients, then the new diluted mixture may be assigned to the same packing group as the original tested mixture. In certain cases, diluting a mixture or substance may lead to an increase in the corrosive properties. If this is the case, this bridging principle cannot be used.

(ii) *Batching.* The skin corrosion potential of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the skin corrosion potential of the untested batch has changed. If the latter occurs, a new classification is necessary.

(iii) Concentration of mixtures of packing group I. If a tested mixture meeting the criteria for inclusion in Packing Group I is concentrated, the more concentrated untested mixture may be assigned to Packing Group I without additional testing.

(iv) Interpolation within one packing group. For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same skin corrosion packing group, and where untested mixture C has the same Class 8 ingredients as mixtures A and B but has concentrations of Class 8 ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same skin corrosion packing group as A and B.

(v) Substantially similar mixtures. Given the following:

(A) Two mixtures: (A+B) and (C+B);

(B) The concentration of ingredient B is the same in both mixtures;

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(C) The concentration of ingredient A in mixture (A+B) equals the concentration of ingredient C in mixture (C+B):

(D) Data on skin corrosion for ingredients A and C are available and substantially equivalent, *i.e.*, they are the same skin corrosion packing group and do not affect the skin corrosion potential of B.

(E) If the above mixture (A+B) or (C+B) is already classified based on test data, then the other mixture may be assigned to the same packing group.

(2) Calculation method based on the classification of the substances. Where a mixture has not been tested to determine its skin corrosion potential, nor is sufficient data available on similar mixtures, the corrosive properties of the substances in the mixture shall be considered to classify and assign a packing group. Applying the calculation method is only allowed if there are no synergistic effects that make the mixture more corrosive than the sum of its substances. This restriction applies only if Packing Group II or III would be assigned to the mixture.

(i) All Class 8 ingredients present at a concentration of  $\geq 1\%$  shall be taken into account, or < 1% if these ingredients are still relevant for classifying the mixture to be corrosive to skin.

(ii) To determine whether a mixture containing corrosive substances must

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be considered a corrosive mixture and to assign a packing group, the calculation method in the flow chart in appendix I must be applied. For this calculation method, generic concentration limits apply where 1% is used in the first step for the assessment of the packing group I substances, and where 5% is used for the other steps respectively.

(iii) When a specific concentration limit (SCL) is assigned to a substance following its entry in the Hazardous Materials Table or in a special provision, this limit shall be used instead of the generic concentration limits (GCL).

(iv) The following formula must be used for each step of the calculation process. The criterion for a packing group is fulfilled when the result of the calculation is  $\geq$  1. The generic concentration limits to be used for the evaluation in each step of the calculation method are those found in appendix I of this part. Where applicable, the generic concentration limit shall be substituted by the specific concentration limit assigned to the substance(s) (SCLi), and the adapted formula is a weighted average of the different concentration limits assigned to the different substances in the mixture:

$$\frac{PGx_1}{GCL} + \frac{PGx_2}{SCL_2} + \ldots + \frac{PGx_i}{SCL_i} \ge 1$$

- PG  $x_i$  = concentration of substance 1, 2 . . .  $\emph{i}$  in the mixture, assigned to packing group x (I, II or III)
- GCL = generic concentration limit
- $SCL_i$  = specific concentration limit assigned to substance *i*

NOTE TO §173.137: When an initial test on either a steel or aluminum surface indicates the material being tested is corrosive, the follow up test on the other surface is not required.

 $[85\ {\rm FR}\ 27880,\ {\rm May}\ 11,\ 2020,\ {\rm as}\ {\rm amended}\ {\rm at}\ 87\ {\rm FR}\ 44993,\ {\rm July}\ 26,\ 2022]$ 

#### §173.140 Class 9—Definitions.

For the purposes of this subchapter, miscellaneous hazardous material (Class 9) means a material which presents a hazard during transportation but which does not meet the definition of any other hazard class. This class includes:

(a) Any material which has an anesthetic, noxious or other similar property which could cause extreme annoyance or discomfort to a flight crew member so as to prevent the correct performance of assigned duties; or

(b) Any material that meets the definition in §171.8 of this subchapter for an elevated temperature material, a