Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Transport of Dangerous Goods 29 November 2016

Fiftieth session
Geneva, 28 November-6 December 2016
Item 2 (c) of the provisional agenda
Recommendations made by the Sub-Committee on its forty-seventh, forty-eighth and forty-ninth sessions and pending issues: listing, classification and packing

Consolidated text for the revised chapter 2.8

Transmitted by the expert from Canada, the European Chemical Industry Council (CEFIC) and the International Association for Soaps, Detergents and Maintenance Products (AISE)

1. This documents presents the text from ST/SG/AC.10/C.3/2016/21/Corr.1, adopted in June 2016 by the UNSCETDG.

2. It integrates the proposed changes from ST/SG/AC.10/C.3/2016/50 regarding: a) the changes in definition as adopted by the Sub Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals, and b) the introduction of explanatory text for specific concentration limits.

3. As discussed in plenary session, some small editorial amendments have been made for consistency and clarity.

4. The changes proposed ST/SG/AC.10/C.3/2016/50 are shown in underlined text using the adopted text from ST/SG/AC.10/C.3/2016/21/Corr.1, and text that amends ST/SG/AC.10/C.3/2016/50 is indicated in red underlined text.

Annex

Amend Chapter 2.8 to read as follows:

"CHAPTER 2.8

CLASS 8 – CORROSIVE SUBSTANCES

2.8.1 Definition and general provisions

2.8.1.1 *Corrosive substances* are substances which, by chemical action, will cause irreversible damage to the skin, or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport.

2.8.1.2 For substances and mixtures that are corrosive to skin, general classification provisions are provided in section 2.8.2. [Skin corrosion refers to the production of irreversible damage to the skin, namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.] ~~[A substance is corrosive to skin when it leads to the destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure for up to 4 hours.]~~

2.8.1.3 Liquids and solids which may become liquid during transport, which are judged not to be skin corrosive shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.3.3 (c) (ii).

2.8.2 General classification provisions

2.8.2.1 Substances and mixtures of Class 8 are divided among the three packing groups according to their degree of danger in transport:

(a) *Packing group I* is assigned to very dangerous substances and mixtures;

(b) *Packing group II* is assigned to substances and mixtures presenting medium danger;

(c) *Packing group III* is assigned to substances and mixtures that present minor danger.

2.8.2.2 Allocation of substances listed in the Dangerous Goods List in Chapter 3.2 to the packing groups in Class 8 has been made on the basis of experience taking into account such additional factors as inhalation risk (see 2.8.2.4) and reactivity with water (including the formation of dangerous decomposition products).

2.8.2.3 New substances and mixtures can be assigned to packing groups on the basis of the length of time of contact necessary to produce <u>irreversible damage of intact skin tissue</u> ~~[full thickness destruction of human skin]~~ in accordance with the criteria in 2.8.3. Alternatively, for mixtures, the criteria in 2.8.4 can be used.

2.8.2.4 A substance or mixture meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC_{50}) in the range of packing group I, but toxicity through oral ingestion or dermal contact only in the range of packing group III or less, shall be allocated to Class 8 (see note under 2.6.2.2.4.1).

2.8.3 Packing group assignment for substances and mixtures

2.8.3.1 Existing human and animal data including information from single or repeated exposure shall be the first line of evaluation, as they give information directly relevant to effects on the skin.

2.8.3.2 In assigning the packing group in accordance with 2.8.2.3, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404[1] or 435[2]. A substance or mixture which is determined not to be corrosive in accordance with OECD Test Guideline 430[3] or 431[4] may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

2.8.3.3 Packing groups are assigned to corrosive substances in accordance with the following criteria (see table 2.8.3.4):

(a) Packing group I is assigned to substances that cause irreversible damage ~~[full thickness destruction]~~ of intact skin tissue within an observation period up to 60 minutes starting after the exposure time of three minutes or less;

(b) Packing group II is assigned to substances that cause irreversible damage ~~[full thickness destruction]~~ of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than three minutes but not more than 60 minutes;

(c) Packing group III is assigned to substances that:

(i) Cause irreversible damage ~~[full thickness destruction]~~ of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or

(ii) are judged not to cause irreversible damage ~~[full thickness destruction]~~ of intact skin tissue but which exhibit a corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials. For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR (1.0144 resp. St 44-3), ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for testing aluminium, non-clad, types 7075–T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the Manual of Tests and Criteria, Part III, Section 37.

NOTE: *Where an initial test on either steel or aluminium indicates the substance being tested is corrosive the follow up test on the other metal is not required.*

Table 2.8.3.4: Table summarizing the criteria in 2.8.3.3

Packing Group	Exposure Time	Observation Period	Effect
I	≤ 3 min	≤ 60 min	irreversible damage ~~[full thickness destruction]~~ of intact skin
II	> 3 min ≤ 1 h	≤ 14 d	irreversible damage ~~[full thickness destruction]~~ of intact skin

[1] *[OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2015]*

[2] *[OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2015]*

[3] *[OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2015]*

[4] *[OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2015]*

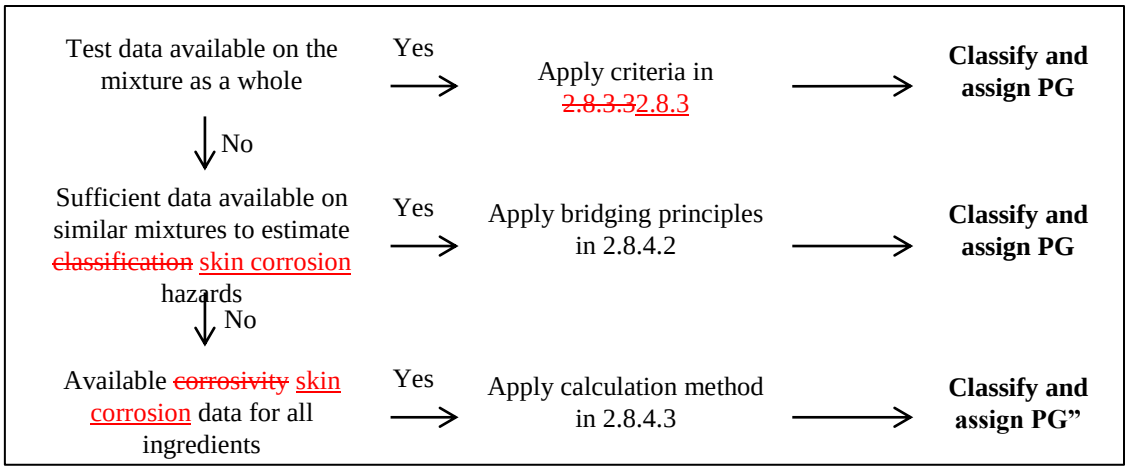
III	> 1 h ≤ 4 h	≤ 14 d	irreversible damage ~~[full thickness destruction]~~ of intact skin
III	-	-	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 ºC when tested on both materials

2.8.4 Alternative packing group assignment methods for mixtures: Step-wise approach

2.8.4.1 *General provisions*

2.8.4.1.1 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 of Figure 2.8.4.1 below outlines the process to be followed:

Figure 2.8.4.1: Step-wise approach to classify and assign packing group of corrosive mixtures



2.8.4.2 *Bridging principles*

2.8.4.2.1 Where a mixture has not been tested to determine its skin corrosion potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately classify and assign a packing group for the mixture, these 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.

(a) **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.

NOTE: *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.*

(b) **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.

(c) **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.

(d) **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.

(e) **Substantially similar mixtures:** Given the following:

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

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

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

(iv) Data on skin corrosion for 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.

If 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.

2.8.4.3 *Calculation method based on the classification of the substances*

2.8.4.3.1 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. ~~This is possible when all substances in the mixture (i.e. present in concentrations of >1%) are considered for classification in accordance with [Chapter 2].~~

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.

2.8.4.3.2 When using the calculation method, all Class 8 ingredients present at a concentration of ≥ 1% shall be taken into account, or <1% if these ingredients are still relevant for classifying the mixture to be corrosive to skin.

2.8.4.3.3 To determine whether a mixture containing corrosive substances shall be considered a corrosive mixture and to assign a packing group, the calculation method in the flow chart in Figure 2.8.4.3 shall be applied. ~~When a specific concentration limit is assigned to a substance following its entry in the Dangerous Goods List or in a Special Provision, this limit shall be used instead of the generic limits in Figure 2.8.4.3. for that substance.~~

~~[insert example/explanation on specific concentration limits here]~~

2.8.4.3.4 When a specific concentration limit (SCL) is assigned to a substance following its entry in the Dangerous Goods List or in a Special Provision, this limit ~~must~~ shall be used instead of the generic concentration limits (GCL). This ~~is~~ appears where 1% is used in the first step for the assessment of the PGI substances, and where 5% is used for the other steps respectively in Figure 2.8.4.3.

2.8.4.3.5 For this purpose, the summation formula for each step of the calculation method ~~must~~ shall be adapted. This means that, where applicable, the generic concentration limit ~~must~~ 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:

$$\frac{PGx1}{GCL} + \frac{PGx2}{SCL2} + \cdots + \frac{PGxi}{SCLi} \geq 1$$

Where:

PG xi = concentration of substance 1, 2 …i in the mixture, assigned to packing group x (I, II or III)

GCL = generic concentration limit

SCLi = specific concentration limit assigned to substance i

The criterion for a packing group is fulfilled when the result of the calculation is ≥ 1. The generic concentration limits to be used for the evaluation in each step of the calculation method are those found in Figure 2.8.4.3.

Examples for the application of the above formula can be found in the note below.

Note: *Examples for the application of the above formula*

Example 1: A mixture contains one corrosive substance in a concentration of 5% assigned to PG I without a specific concentration limit:
Calculation for PG I: $\frac{5}{5\ (GCL)} = 1$ ➔ *assign to class 8, PG I*
:
Example 2: A mixture contains three substances corrosive to skin: two of them (A and B) have specific concentration limits; for the third one (C) the generic concentration limits applies. The rest of the mixture needs not to be taken into consideration:

Substance X in the mixture and its PG assignment within class 8	*Concentration (conc)in the mixture in %*	*Specific concentration limit (SCL)for PG I*	*Specific concentration limit (SCL) for PG II*	*Specific concentration limit (SCL) for PG III*
A, assigned to PG I	*3*	*30%*	*none*	*none*
B, assigned to PG I	*2*	*20%*	*10%*	*none*
C, assigned to PG III	*10*	*none*	*none*	*none*

Calculation for packing group I: $\frac{3\ (conc\ A)}{30\ (SCL\ PGI)} + \frac{2\ (conc\ B)}{20\ (SCL\ PGI)} = 0{,}2 < 1$

The criterion for packing group I is not fulfilled.

Calculation for packing group II: $\frac{3\ (conc\ A)}{5\ (GCL\ PG\ II)} + \frac{2\ (conc\ B)}{10\ (SCL\ PG\ II)} = 0{,}8 < 1$

The criterion for packing group II is not fulfilled.

Calculation for packing group III: $\frac{3\ (conc\ A)}{5\ (GCL\ PGIII)} + \frac{2\ (conc\ B)}{5\ (GCL\ PG\ III)} + \frac{10\ (conc\ C)}{5\ GCL\ PG\ III)} = 3 \geq 1$

The criterion for packing group III is fulfilled, the mixture shall be assigned to class 8, packing group III.

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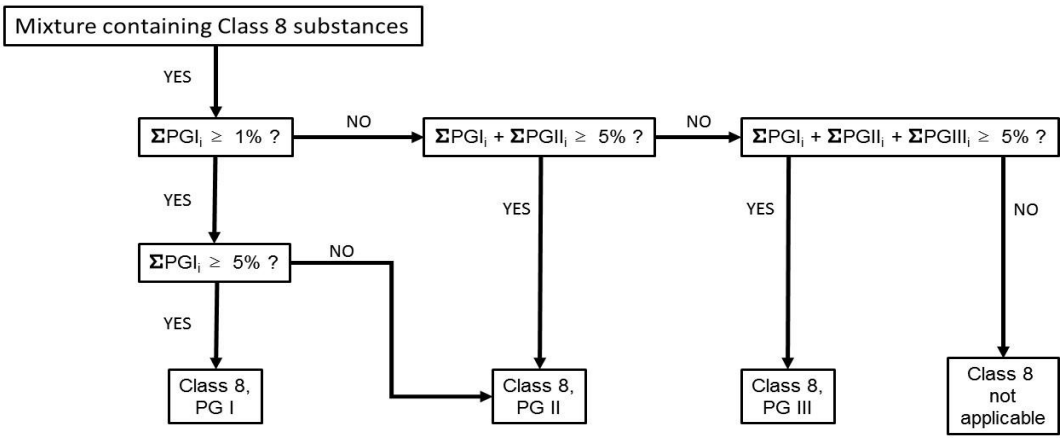
Figure 2.8.4.3: Calculation method



2.8.5 Substances not accepted for transport

Chemically unstable substances of Class 8 shall not be accepted for transport unless the necessary precautions have been taken to prevent the possibility of a dangerous decomposition or polymerization under normal conditions of transport. For the precautions necessary to prevent polymerization, see special provision 386 of Chapter 3.3. To this end particular care shall be taken to ensure that receptacles and tanks do not contain any substances liable to promote these reactions.