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Item 2 (d) of the provisional agenda
Classification criteria and related hazard communication: Work of the TDG-GHS working group on corrosivity criteria

Proposal for revision of Chapter 2.8 of the Model Regulations

Transmitted by the expert from the Netherlands

Introduction

1. Reference is made to document ST/SG/AC.10/C.3/2014/69–ST/SG/AC.10/C.4/2014/12.

2. For ease of reference, the Annex to this paper presents the text of the proposed new Chapter 2.8 in visible mode (track changes). The text of the new Chapter 2.8 was developed on the basis of the current text in Chapter 2.8 of the Model Regulations (Rev.18) and on Chapter 3.2 of the GHS (Rev.5).

Annex

References for the proposed new text to Chapter 2.8 in paragraph 7 of document ST/SG/AC.10/C.3/2014/69– ST/SG/AC.10/C.4/2014/12

***NOTE**: References to existing texts are to paragraphs in Chapter 3.2 of GHS (Rev.5) and to paragraphs in Chapter 2.8 of the Model Regulations (Rev.18). All changes are indicated.*

"CHAPTER 2.8

CLASS 8 – CORROSIVE SUBSTANCES

~~3.2.1~~2.8.1 Definitions and general ~~considerations~~provisions

~~3.2.1.1~~ 2.8.1.1 *Class 8 (corrosive) substances* are substances which, by chemical action, lead to ~~*Skin corrosion is*~~ the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours~~[†].~~ ~~Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions~~ and observation periods of up to 14 days, or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport.

~~*Skin irritation* is the production of reversible damage to the skin following the application of a test substance for up to 4 hours[†].~~

2.8.1.2 For substances and mixtures that are corrosive to skin, hazard classification is determined using criteria in section 2.8.2. Substances or mixtures shall be classified in one of the three sub-classification 8A, 8B or 8C. Where the available data do not allow sub-classification, substances and mixtures shall be assigned to Class 8 without sub-classification. Substances and mixtures corrosive to skin are assigned to a packing group using criteria in section 2.8.3.

***NOTE:** The sub-classifications 8A, 8B and 8C do not constitute divisions in Class 8.*

~~2.8.2.2~~2.8.1.3 ~~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 2.8.2.3) and reactivity with water (including the formation of dangerous decomposition products). New substances, including mixtures, can be assigned to packing groups on the basis of the length of time of contact necessary to produce full thickness destruction of human skin in accordance with the criteria in 2.8.2.4.~~ Liquids, and solids which may become liquid during transport, which are judged not to be skin corrosive~~cause full thickness destruction of human skin~~ shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in ~~2.8.2.5 (c) (ii)~~2.8.4.

~~2.8.2.3~~2.8.1.4 A substance or ~~preparation~~ a 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).

~~3.2.~~**2.8.2 Criteria for hazard classification of substances or mixtures as corrosive to skin**

~~[†] *This is a working definition for the purpose of this document.*~~

~~3.2.1.2~~2.8.1.3 For hazard classification of a substance or a mixture into Class 8, all available information on corrosive properties of a substance or a mixture shall be taken into account in a tiered approach (see 2.8.2.2). ~~In a tiered approach,~~ Eemphasis ~~should~~ shall be placed upon existing human data, followed by existing animal data, followed by *in vitro* data and then other sources of information. Classification results directly when the data satisfy the criteria. In some cases, classification of a substance or a mixture is made on the basis of the weight of evidence within a tier. In a total weight of evidence approach all available information bearing on the determination of skin corrosion~~/irritation~~ is considered together, including the results of appropriate validated *in vitro* tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations ~~(see Chapter 1.3, para. 1.3.2.4.9).~~.

~~3.2.2.1~~2.8.2.1 ~~*Classification*~~ ***Hazard classification corrosive to skin*** ***based on standard animal test data***

~~3.2.2.1.1 Skin corrosion~~

~~3.2.2.1.1.1~~ 2.8.2.1.1 A substance is corrosive to skin when it produces 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. An example of an internationally accepted validated test method for skin corrosion is OECD Test Guideline 404[1] .

~~3.2.2.1.1.2 Corrosive substances should be classified in Category 1 where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization.~~

~~3.2.2.1.1.3 When data are sufficient and where required by a competent authority substances may be classified in one of the three sub-categories 1A, 1B or 1C in accordance with the criteria in Table 3.2.1.~~

~~3.2.2.1.1.4~~ 2.8.2.1.2 ~~For those authorities wanting more than one designation for skin corrosion, up to~~ Three sub-categories are provided within the corrosion ~~category (Category 1~~Class (Class 8, see Table ~~3.~~2.8.1): ~~sub-category 1A~~Class 8A, where corrosive responses are noted following up to 3 minutes exposure and up to 1 hour observation; ~~sub-category 1B~~Class 8B, where corrosive responses are described following exposure greater than 3 minutes and up to 1 hour and observations up to 14 days; and ~~sub-category 1C~~Class 8C, where corrosive responses occur after exposures greater than 1 hour and up to 4 hours and observations up to 14 days.

Table ~~3.2.1~~2.8.1: Skin corrosion hazard ~~category and sub-categories~~[a] classifications[a]

	Criteria
~~Category 1~~Class 8	Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure ≤ 4 h
~~Sub-category 1A~~Class 8A	Corrosive responses in at least one animal following exposure ≤ 3 min during an observation period ≤ 1 h
~~Sub-category 1B~~Class 8B	Corrosive responses in at least one animal following exposure > 3 min and ≤ 1 h and observations ≤ 14 days
~~Sub-category 1C~~Class 8C	Corrosive responses in at least one animal after exposures > 1 h and ≤ 4 h and observations ≤ 14 days

[a] *The use of human data is addressed in GHS 3.2.2.2 and in GHS chapters 1.1 (para. 1.1.2.5 (c)) and 1.3 (para. 1.3.2.4.7).*

[1] *OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2002.*

~~3.2.2.2~~2.8.2.2 ~~Hazard~~ Hazard classification in a tiered approach

~~3.2.2.2.1~~2.8.2.2.2 A *tiered approach* to the evaluation of initial information ~~should~~shall be considered, where applicable (Figure ~~3.~~2.8.1), recognizing that not all elements may be relevant.

~~3.2.2.2.2~~2.8.2.2.3 Existing human and animal data including information from single or repeated exposure ~~should~~shall be the first line of evaluation, as they give information directly relevant to effects on the skin.

~~3.2.2.2.3~~2.8.2.2.3 Acute dermal toxicity data may be used for classification. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion~~/irritation~~ in acute toxicity studies and are observed up through the limit dose, these data ~~may~~shall be used for classification~~,~~ provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes.

~~3.2.2.2.4~~2.8.2.2.4 *In vitro* alternatives that have been validated and accepted ~~should~~can be used to make classification decisions. Examples of internationally accepted validated test methods for skin corrosion include OECD Test Guidelines 430[2] (Transcutaneous Electrical Resistance Test (TER)), 431[3] (Human Skin Model Test) and 435 (Membrane Barrier Test Method)[4]. Some *in vitro* tests are suitable to sub-classify. A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430 or 431 may be considered not to be corrosive to skin for the purposes of these Regulations.

~~3.2.2.2.5~~2.8.2.2.5 Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (~~Skin Category 1~~Class 8) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of acid/alkaline reserve[5] suggests the substance may not be corrosive despite the low or high pH value, this needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.

~~3.2.2.2.6~~2.8.2.2.6 In some cases sufficient information may be available from structurally related substances to make classification decisions.

~~3.2.2.2.7~~2.8.2.2.7 The tiered approach provides guidance on how to organize existing information on a substance and to make a weight of evidence decision about hazard assessment and hazard classification (ideally without conducting new animal tests). Although information might be gained from the evaluation of single parameters within a tier (see ~~3.~~2.8.2.2.1), consideration ~~should~~shall be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

[2] *OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" [2004][2013].*

[3] *OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" [2004][2013].*

[4] *OECD Guideline for the testing of chemicals No. 435 "Membrane Barrier Test Method" 2006.*

[5] *Acid/Alkaline reserve may be determined e.g. by the methodology detailed in Young J.R., How M.J., Walker A.P., Worth W.M.H. (1988): Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without testing on animals. Toxicology in Vitro **2**, 19-26 and Young J.R., How M.J. (1994): Product classification as corrosive or irritant by measuring pH and acid / alkali reserve. In Alternative Methods in Toxicology vol. 10 - In Vitro Skin Toxicology: Irritation, Phototoxicity, Sensitization, eds. A.Rougier, A.M. Goldberg and H.I.Maibach, Mary Ann Liebert, Inc. 23-27.*

Figure ~~3.2.1~~2.8.1: Tiered evaluation for skin corrosion ~~and irritation~~

Step	Parameter	Finding	Conclusion
1a:	Existing human or animal skin corrosion~~/irritation~~ data [a] → ↓ Not corrosive/No data ↓	Skin corrosive →	Classify as **skin corrosive** [b]
~~**1b:**~~	~~Existing human or animal skin corrosion/irritation data~~ [a] → ↓ ~~Not irritant/No data~~ ↓	~~Skin irritant~~ →	~~Classify as **skin irritant**~~ [b]
~~**1c**~~**1b:**	Existing human or animal skin corrosion~~/irritation~~ data [a] → ↓ No/Insufficient data ↓	Not a skin corrosive ~~or skin irritant~~ →	**Not classified**
2:	Other~~,~~ existing skin data in animals [c] → ↓ No/Insufficient data ↓	Yes; other existing data showing that substance may cause skin corrosion ~~or skin irritation~~ →	May be deemed to be a **skin corrosive** [b] ~~or a **skin irritant**~~ [b]
3:	Existing *ex vivo/in vitro* data [d] → ↓ → ↘ No/Insufficient data/Negative response ↓	Positive on corrosivity: Skin corrosive → ~~Positive: Skin irritant~~ →	Classify as **skin corrosive** [b] ~~Classify as **skin irritant**~~ [b]
4:	pH-Based assessment (with consideration of acid/alkaline reserve of the chemical) [e] → ↓ Not pH extreme, no pH data or extreme pH with data showing low/no acid/alkaline reserve ↓	pH ≤ 2 or ≥ 11.5 with high acid/alkaline reserve or no data for acid/alkaline reserve →	Classify as **skin corrosive**
5:	Validated Structure Activity Relationship (SAR) methods → ↓ → ↘ No/Insufficient data ↓	Skin corrosive → ~~Skin irritant~~ →	Deemed to be **skin corrosive** [b] ~~Deemed to be **skin irritant**~~ [b]
6:	Consideration of the total weight of evidence [f] → ↓ → ↘	Skin corrosive → ~~Skin irritant~~ →	Deemed to be **skin corrosive** [b] ~~Deemed to be **skin irritant**~~ [b]
7:	**Not classified**		

~~(~~[a]~~)~~ *Existing human or animal data could be derived from single or repeated exposure(s), for example in occupational, consumer, transport, or emergency response scenarios; or from purposely-generated data from animal studies conducted according to validated and internationally accepted test methods. Although human data from accident or poison centre databases can provide evidence for classification, absence of incidents is not itself evidence for no classification as exposures are generally unknown or uncertain;*

~~(~~[b]~~)~~ *Classify in ~~the appropriate category~~Class 8/sub-~~category~~classification, as applicable;*

~~(~~[c]~~)~~ *All existing animal data ~~should~~shall be carefully reviewed to determine if sufficient skin corrosion~~/irritation~~ evidence is available. In evaluating such data, however, the reviewer ~~should~~shall bear in mind that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses;*

~~(~~[d]~~)~~ *Evidence from studies using validated protocols with isolated human/animal tissues or other, non-tissue-based, though validated, protocols ~~should~~shall be assessed. Examples of internationally accepted, validated test methods for skin corrosion include OECD Test ~~Guidelines~~Guideline 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test Method). ~~An example of a validated internationally accepted in vitro test method for skin irritation is OECD Test Guideline 439 (Reconstructed Human Epidermis Test Method);~~*

~~(~~[e]~~)~~ *Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently, there is no validated and internationally accepted method for assessing this parameter;*

~~(~~[f]~~)~~ *All information that is available ~~should~~shall be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. Expert judgment ~~should~~shall be exercised prior to making such a determination. Negative results from applicable validated skin corrosion/irritation in vitro tests are considered in the total weight of evidence evaluation.*

~~3.2.3~~2.8.2.3 ***Hazard classification criteria for mixtures***

~~3.2.3.1~~2.8.2.3.1 *Hazard classification of mixtures when data are available for the complete mixture*

~~3.2.3.1.1~~2.8.2.3.1.1 The mixture ~~should~~shall be classified using the criteria for substances, taking into account the tiered approach to evaluate data for ~~this hazard class~~Class 8 (as illustrated in Figure ~~3.~~2.8.1).

~~3.2.3.1.2~~2.8.2.3.1.2 When considering testing of the mixture, classifiers are encouraged to use a tiered weight of evidence approach as included in the criteria for classification of substances for skin corrosion ~~and irritation~~ to help ensure an accurate classification, as well as to avoid unnecessary animal testing. In the absence of any other information, a mixture is considered corrosive (~~Skin Category 1~~Class 8) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of acid/alkaline reserve[6] suggests the mixture may not be corrosive despite the low or high pH value, this needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.

~~3.2.3.2~~2.8.2.3.2 *Hazard classification of mixtures when data are not available for the complete mixture: bridging principles*

[6] *Acid/Alkaline reserve may be determined e.g. by the methodology detailed in Young J.R., How M.J., Walker A.P., Worth W.M.H. (1988): Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without testing on animals. Toxicology in Vitro **2**, 19-26 and Young J.R., How M.J. (1994): Product classification as corrosive or irritant by measuring pH and acid / alkali reserve. In Alternative Methods in Toxicology vol. 10 - In Vitro Skin Toxicology: Irritation, Phototoxicity, Sensitization, eds. A.Rougier, A.M. Goldberg and H.I.Maibach, Mary Ann Liebert, Inc. 23-27.*

~~3.2.3.2.1~~2.8.2.3.2.1 Where the mixture itself has not been tested to determine its skin corrosion~~/ irritation~~ potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

~~3.2.3.2.2~~2.8.2.3.2.2 Dilution

If a tested mixture is diluted with a diluent which has an equivalent or lower ~~skin~~ corrosivity~~/irritancy~~ classification than the least ~~skin~~ corrosive~~/irritant~~ original ingredient and which is not expected to affect the ~~skin~~ corrosivity~~/irritancy~~ of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture. Alternatively, the method explained in ~~3~~2.8.2.3.3 could be applied.

~~3.2.3.2.3~~2.8.2.3.2.3 Batching

The skin corrosion~~/irritation~~ 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~~/irritation~~ potential of the untested batch has changed. If the latter occurs, a new classification is necessary.

~~3.2.3.2.4~~2.8.2.3.2.4 Concentration of mixtures of the highest corrosion~~/irritation category~~ sub-classification

If a tested mixture classified in the highest sub-~~category~~classification for skin corrosion is concentrated, the more concentrated untested mixture ~~should~~shall be classified in the highest corrosion sub-~~category~~classification without additional testing.

~~If a tested mixture classified for skin irritation (Category 2) is concentrated and does not contain skin corrosive ingredients, the more concentrated untested mixture should be classified for skin irritation (Category 2) without additional testing.~~

~~3.2.3.2.5~~2.8.2.3.2.5 Interpolation within one ~~hazard~~ sub-classification

For three mixtures (~~A~~X, ~~B~~ Y and ~~C~~Z) with identical ingredients, where mixtures ~~A~~ X and ~~B~~ Y have been tested and are in the same skin corrosion~~/irritation hazard category~~ sub-classification, and where untested mixture ~~C~~ Z has the same toxicologically active ingredients as mixtures ~~A~~ X and ~~B~~Y but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures ~~A~~ X and ~~B~~Y, then mixture ~~C~~ Z is assumed to be in the same skin corrosion~~/irritation category~~ sub-classification as ~~A~~ X and ~~B~~Y.

~~3.2.3.2.6~~2.8.2.3.2.6 Substantially similar mixtures

Given the following:

(a) Two mixtures: (i) ~~A~~ X + ~~B~~Y;
(ii) ~~C~~ Z + ~~B~~Y;

(b) The concentration of ingredient ~~B~~ Y is essentially the same in both mixtures;

(c) The concentration of ingredient ~~A~~ X in mixture (i) equals that of ingredient ~~C~~ Z in mixture (ii);

(d) Data on skin corrosion~~/irritation~~ for ~~A~~ X and ~~C~~ Z are available and substantially equivalent, i.e. they are in the same ~~hazard category~~sub-classification and are not expected to affect the skin corrosion~~/irritation~~ potential of ~~B~~Y.

If mixture (i) or (ii) is already classified based on test data, then the other mixture can be classified in the same ~~hazard category~~sub-classification.

~~3.2.3.2.7 *Aerosols*~~

~~An aerosol form of a mixture may be classified in the same hazard category as the tested non-aerosolized form of the mixture provided that the added propellant does not affect the skin corrosion/irritation properties of the mixture upon spraying.~~

~~3.2.3.~~2.8.2.3.3 ~~*Hazard* classification~~ *of mixtures when data are available for all ingredients or only for some ingredients of the mixture*

~~3.2.3.3.1~~2.8.2.3.3.1 In order to make use of all available data for purposes of classifying the skin corrosion~~/irritation~~ hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach:

The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases), unless there is a presumption ~~(e.g. in the case of corrosive ingredients)~~ that an ingredient present at a concentration < 1% can still be relevant for classifying the mixture for skin corrosion~~/irritation~~.

~~3.2.3.3.2~~2.8.2.3.3.2 Additivity

In general, the approach to classification of mixtures as corrosive ~~or irritant~~ to skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each skin corrosive ~~or irritant~~ ingredient contributes to the overall corrosive ~~or irritant~~ properties of the mixture in proportion to its potency and concentration. ~~A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant.~~ The mixture is classified as corrosive ~~or irritant to skin~~ when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

~~3.2.3.3.3 Table 3.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be corrosive or irritant to the skin.~~

~~**NOTE:**~~2.8.2.3.3.3 Where ~~the sub-categories of skin Category 1 (corrosive) are used,~~ the sum of all ingredients of a mixture sub-classified ~~as sub-category 1~~8A, ~~1~~8B or ~~1~~8C ~~respectively, should~~ is each ~~be~~ ≥ 5% ~~in order to classify~~ the mixture shall be classified ~~as either~~ skin ~~sub-category~~ sub-classification ~~1~~8A, ~~1~~8B or ~~1~~8C, respectively. Where the sum of ~~1~~8A ingredients is < 5% but the sum of ~~1~~8A+~~1~~8B ingredients is ≥ 5%, the mixture ~~should~~ shall be classified as sub-~~category~~ classification ~~1~~8B. Similarly, where the sum of ~~1A~~ 8A + ~~1B~~ 8B ingredients is < 5% but the sum of ~~1A~~ 8A + ~~1B~~ 8B + ~~1C~~ 8C ingredients is ≥ 5% the mixture ~~should~~ shall be classified as sub-~~category~~ classification ~~1~~8C. Where at least one relevant ingredient in a mixture is classified as ~~Category 1~~Class 8 without sub-~~categorisation~~classification, the mixture ~~should~~ shall be classified as ~~Category 1~~Class 8 without sub-~~categorisation~~ classification if the sum of all ingredients corrosive to skin is ≥ 5%.

~~3.2.3.3.4~~2.8.2.3.3.4 Non-additivity

Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in ~~3.~~2.~~3.3.1 and 3~~8.2.3.3.2 and 2.8.2.3.3.3 might not work given that many such substances are corrosive ~~or irritant~~ at concentrations < 1%. For mixtures containing strong acids or bases the pH ~~should~~shall be used as classification ~~criteria~~criterion (see ~~3~~2.8.2.3.1.2) since pH will be a better indicator of corrosion than the concentration limits in ~~Table~~ 2.8.2.3.3.3.~~2.3.~~ A mixture containing corrosive ~~or irritant~~ ingredients that cannot be classified based on the additivity approach ~~shown in Table 3.2.3,~~ due to chemical characteristics that make this approach unworkable, ~~should~~shall be classified as ~~skin corrosion Category 1~~Class 8 if it contains ≥ 1% of a corrosive ingredient ~~and as skin irritation Category 2 or Category 3 when it contains~~

~~≥ 3% of an irritant ingredient.~~ Classification of mixtures with ingredients for which the approach in ~~Table~~ 2.8.2.3.~~2~~3.3 does not apply is summarized in Table ~~3.~~2.~~4~~8.2 below.

~~3.2.3.3.5~~2.8.2.3.3.5 Exemptions

On occasion, reliable data may show that the skin corrosion~~/irritation~~ of an ingredient will not be evident when present at a level above the generic concentration limits/cut-off values mentioned in ~~Tables 3.~~2.8.2.3.3.3 and Table 2.8.2.~~2.4.~~ In these cases the mixture ~~could~~may be classified according to those data ~~(see also *Classification of hazardous substances and mixtures – Use of cut-off values/Concentration limits* (1.3.3.2)).~~ On occasion, when it is expected that the skin corrosion~~/irritation~~ of an ingredient will not be evident when present at a level above the generic concentration cut-off values mentioned in ~~Tables 3.~~2.8.2.3.3.3 and ~~3.~~ Table 2.~~4~~8.2, testing of the mixture may be considered. In those cases the tiered weight of evidence approach ~~should~~shall be applied as described in ~~3.~~2.~~3~~8.2.2 and illustrated in Figure ~~3.~~2.8.1~~.~~

~~3.2.3.3.6~~2.8.2.3.3.6 If there are data showing that (an) ingredient(s) may be corrosive ~~or irritant~~ to skin at a concentration of < 1% (corrosive) ~~or < 3% (irritant),~~ the mixture ~~should~~shall be classified accordingly ~~(see also *Classification of hazardous substances and mixtures – Use of cut-off values/Concentration limits* (1.3.3.2)).~~

Table 2.8.2: Concentration of ingredients of a mixture when the additivity approach does not apply, that would trigger classification of the mixture as ~~hazardous~~corrosive to skin

Ingredient	Concentration	Mixture classified as ~~Skin~~
Acid with pH ≤ 2	≥ 1%	~~Category 1~~Class 8
Base with pH ≥ 11.5	≥ 1%	~~Category 1~~Class 8
Other skin corrosive (~~Category 1~~Class 8) ingredient	≥ 1%	~~Category 1~~Class 8
~~Other irritant (Category 2/3) ingredient, including acids and bases~~	~~≥ 3%~~	~~Category 2/3~~

2.8.~~2~~3 Assignment of packing groups

2.8.~~2~~3.1 Substances and ~~preparations~~ mixtures of Class 8 are divided among the three packing groups according to their degree of ~~hazard~~ danger in transport as follows:

(a) *Packing group I:* Very dangerous substances and ~~preparations~~mixtures;

(b) *Packing group II*: Substances and ~~preparations~~ mixtures presenting medium danger;

(c) *Packing group III*: Substances and ~~preparations~~ mixtures presenting minor danger.

2.8.~~2~~3.2 Allocation of substances and mixtures 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 ~~2.8.2.3~~2.8.1.4) and reactivity with water (including the formation of dangerous decomposition products). ~~New substances, including mixtures, can be assigned to packing groups on the basis of the length of time of contact necessary to produce full thickness destruction of human skin in accordance with the criteria in 2.8.2.4. Liquids, and solids which may become liquid during transport, which are judged not to cause full thickness destruction of human skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.2.5 (c) (ii).~~

2.8.3.3 Unless otherwise specified in section 2.8.3.4 to 2.8.3.5, substances and mixtures not listed by name in the Dangerous Goods List shall be assigned to packing groups based on their classification into Class 8A, 8B or 8C.

(a) Substances and mixtures classified as Class 8A are assigned to packing group I

(b) Substances and mixtures classified as Class 8B are assigned to packing group II

(c) Substances and mixtures classified as Class 8C are assigned to packing group III

(d) Substances and mixtures classified as Class 8 without sub-classification are assigned to packing group I

2.8.3.4 Notwithstanding 2.8.3.3, the packing group of mixtures classified as Class 8A based on additivity calculations (see 2.8.2.3.3.2 and 2.8.2.3.3.3) may be assigned using the following method:

(a) Derive the packing group for each individual ingredient. For substances listed by name in the Dangerous Goods List, the packing group shall be taken directly from the list. For substances not listed by name, the packing group from the most appropriate n.o.s entry shall be used;

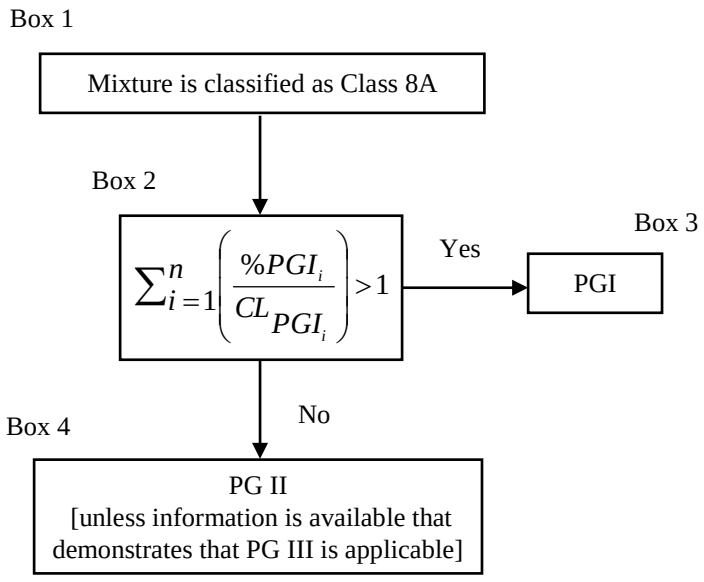
(b) Identify the specific or generic concentration threshold for each individual ingredient. For some substances listed by name on the Dangerous Goods List, the concentration threshold can be taken directly from the list. If no specific concentration threshold is available, generic concentration threshold listed in Table 2.8.3 shall be used;

(c) Assign the packing group for the mixture in accordance with flow scheme 2.8.1 [unless information is available that demonstrates that packing group III is applicable].

Table 2.8.3: Generic concentration limit for determination of the packing group of mixtures classified as 8A using the additivity calculations

Generic concentration limit	Concentration
CL PG I	[5%]

Figure 2.8.2: Flow chart scheme for assignment of packing group for mixtures with hazard classification 8A based on additivity calculations



Notes to Figure 2.8.2:
% PG I_i is the concentration of ingredient i assigned to packing group I

$CL_{PG\ Ii}$ is the concentration limit on Dangerous Goods List for ingredient i with packing group I. This concentration limit can be either a specific concentration limit from the Dangerous Goods List or generic concentration limit from Table 2.8.3.

2.8.3.5 Notwithstanding 2.8.3.3, substances and mixtures classified as Class 8 without sub-classification may be assigned using the following method:

(a) Derive the packing group for each individual ingredient. For substances listed by name in the Dangerous Goods List, the packing group shall be taken directly from the list. For substances not listed by name, the packing group from the most appropriate n.o.s. entry shall be used;

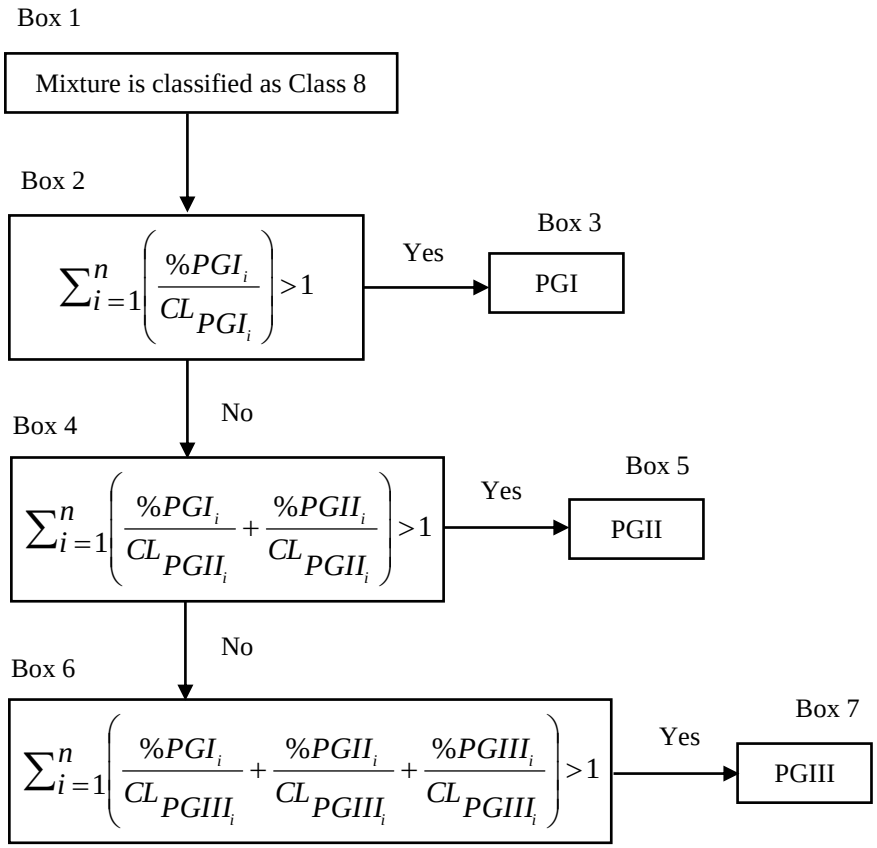
(b) Identify the specific or generic concentration threshold for each individual ingredient. For some substances listed by name on the Dangerous Goods List, the concentration threshold can be taken directly from the list. If no specific concentration threshold is available, generic concentration threshold listed in Table 2.8.4 shall be used;

(c) Assign the packing group for the mixture in accordance with Figure 2.8.3.

Table 2.8.4: Generic concentration limit for determination of the packing group of mixtures classified as Class 8 without sub-classification

Generic Concentration Limit	Concentration
CL PG I	[5%]
CL PG II	[3%]
CL PG III	[1%]

Figure 2.8.3: Flow chart scheme for assignment of packing group for mixtures classified as Class 8 without sub-classification based on non-additivity



Notes to Figure 2.8.3:

% PG I_i is the concentration of ingredient i assigned to packing group I.
% PG II_i is the concentration of ingredient i assigned to packing group II.
% PG III_i is the concentration of ingredient i assigned to packing group III.

$CL_{PG\ Ii}$ is the concentration limit for ingredient i in PG I. This concentration limit can be either a specific concentration limit taken from the Dangerous Goods List or the generic concentration limit from Table 2.8.4.
$CL_{PGI\ Ii}$ is the concentration limit for ingredient i in PG II. This concentration limit can be either a specific concentration limit taken from the Dangerous Goods List or the generic concentration limit from Table 2.8.4.
$CL_{PG\ IIIi}$ is the concentration limit for ingredient i in PG III. This concentration limit can be either a specific concentration limit taken from the Dangerous Goods List or the generic concentration limit from Table 2.8.4.

2.8.4 Corrosive to metals

~~2.8.2.2~~ 2.8.4.1 ~~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 2.8.2.3) and reactivity with water (including the formation of dangerous decomposition products). New substances, including mixtures, can be assigned to packing groups on the basis of the length of time of contact necessary to produce full thickness destruction of human skin in accordance with the criteria in 2.8.2.4.~~ Liquids, and solids which may become liquid during transport, which are judged not to ~~cause full thickness destruction of human~~be corrosive to skin, 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 are assigned to Class 8. ~~shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.2.5 (c) (ii).~~

~~2.8.2.5 (ii)~~ 2.8.4.2 ~~are judged not to cause 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.*

2.8.4.3 Packing group III is assigned in accordance with Table 2.8.5.

Table 2.8.5

Packing Group	**Effect**
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

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