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

20 November 2013

Sub-Committee of Experts on the Transport of Dangerous Goods

Forty-fourth session Geneva, 25 November – 4 December 2013 Item 10 (h) of the provisional agenda Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals: corrosivity criteria Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Twenty-sixth session Geneva, 4 – 6 December 2013 Item 2 (c) of the provisional agenda Classification criteria and hazard communication: corrosivity criteria

### Consistency of classification criteria in the UN Model Regulations and in the GHS: Further consideration of options for a way forward and agenda for the meeting of the joint working group on corrosivity criteria

### Transmitted by the expert from the United Kingdom

### Purpose

1. At the joint meeting in July 2013 the Joint Informal Correspondence Group on corrosivity criteria considered the paper INF.42 (TDG 43rd session) and INF.11 (GHS 25th session) prepared by the expert from the United Kingdom. The Joint Informal Correspondence Group decided to focus on options 2, 5 and 6 as set out in that paper.

2. In line with paragraph (e) of its terms of reference1 to "report findings and make recommendations that meet the needs of all sectors with the aim of achieving consistent classification outcomes for skin corrosivity", this paper sketches out how each of the options 2, 5 and 6 would appear in terms of new and amended text in Chapter 2.8 of the Models Regulations and in Chapter 3.2 in the GHS.

3. An agenda for the meeting of the joint informal correspondence group on corrosivity criteria, to take place on 3 December 2013<sup>2</sup> is in Annex 1 to this document.

### **Development of options**

4. In further developing these options the expert from the United Kingdom has drawn on the previous papers submitted for discussion in the expert group, as summarised in Annex 1.

<sup>&</sup>lt;sup>2</sup> The provisional timetable for the meetings of the informal working groups is circulated as INF.9 (GHS, 26<sup>th</sup> session).



 $<sup>^1\,</sup>$  Refer to ST/SG/AC.10/C.4/48, Annex IV , item 1 (h).

### **Option 2:**

5. This option is shown diagrammatically below. The skin corrosion subcategories 1A, 1B and 1C are removed from the GHS, leaving skin corrosion category 1. Transport adopts these revised GHS criteria, including the alternative methods, to classify as Class 8. Assignment of PG for transport is done by dividing Transport Class 8 into three subcategories designated by PG. Criteria for allocation of PG are set out in Chapter 2.8 of the Model Regulations to secure the desired distribution of PGs I, II and III in multi-modal transport (preserving the status quo) and are not necessarily based only on hazard.

		Classifi	cation	
Classification criteria		GHS	Transport	Other transport conditions
Exposure $\leq$ 3 minutes			Class 8 PG I	~
Observation $\leq 1$ hour				Special packing
Exposure $> 3$ minutes $\le 1$ hour	Alternative methods	Skin corrosive		excepted quantities and
Observation $\leq 14$ days	internative methods	Category 1		downstream transport
Exposure $> 1$ hour $\le 4$ hour			Class 8 PG III	provisions
Observation $\leq 14$ days				

6. To illustrate what this option would look like in practice, <u>Annexes 2 and 3</u> set out a preliminary view of the changes that would be needed in Chapter 3.2 of the GHS and in Chapter 2.8 of the Model Regulations respectively.

### **Option 5:**

7. This option is shown diagrammatically below. Transport adopts the GHS criteria including alternative methods to classify as Class 8. There is no sub-division of hazard in Skin corrosion category 1 or Class 8. PG assignment is a transport condition, not a classification, and is based on hazard and risk-based criteria that maintain the existing distribution of PGs I, II and III for substances and mixtures in multi-modal transport.

		Hazard c	assification		
Classification crit	eria	GHS	Transport	Trans	port conditions
Exposure $\leq 3 \min$				PG I	Special packing
Observation $\leq 1$ hour				DOM	provisions, limited
Exposure > $3 \min \le 1$ hour	Alternative	Skin		PGII	and excepted
Observation $< 14$ days	methods	Corrosive 1	Class 8		quantities and
		Conosive 1			downstream
Exposure > 1 hour $\leq$ 4 hour				PGIII	transport
Observation $\leq 14$ days					provisions

8. To illustrate what this option would look like in practice, <u>Annexes 2 and 4</u> set out a preliminary view of the changes that would be needed in Chapter 3.2 of the GHS and in Chapter 2.8 of the Model Regulations respectively.

### **Option 6:**

9. This option is shown diagrammatically below. Where classification is based on human or animal test data transport adopts the GHS classification criteria, aligning PG I, PG II and PG III with hazard categories 1A, 1B, 1C. Where classification is based on alternative methods, transport classifies as Class 8 but applies other criteria to assign PG.

#### UN/SCETDG/44/INF.29 UN/SCEGHS/26/INF.11

		Table 6		
		Classific	cation	
Classification criteria		GHS	Transport	Other transport conditions
Exposure $\leq 3 \text{ min}$ Observation $\leq 1 \text{ hour}$		Skin Corrosive 1A	Class 8 PG I	Special packing
Exposure > 3 min $\leq$ 1 hour Observation $\leq$ 14 days	Test data	Skin Corrosive 1B	Class 8 PG II	excepted quantities and
Exposure > 1 hour $\leq$ 4 hour Observation $\leq$ 14 days		Skin Corrosive 1C	Class 8 PG III	provisions
		Skin corresive 14*	Class 8 PG I	Special packing
	Alternative	Skin corrosive 1A*       Skin corrosive 1B*	provisions, limited and excepted quantities and	
	methods			
	SI	Skin corrosive 1C*	Class 8 PG III	downstream transport provisions

\* Where alternative methods allow sub-classification

10. To illustrate what this option would look like in practice, <u>Annex 5</u> sets out a preliminary view of the changes that would be needed in Chapter 2.8 of the Model Regulations. At this stage no changes are envisaged to Chapter 3.2 of the GHS under this option.

### **Comparison of options**

- 11. As previously agreed the options should be judged against the criteria that:
  - (a) Classification as skin corrosive is consistent between GHS and transport sectors; and
  - (b) The needs of all sectors are met, including that for transport packing group assignment maintains an appropriate distribution of PGs I, II and III.
- 12. In selecting its preferred option the Joint Informal Correspondence Group may also wish to consider:
  - (a) The wider issue of assigning packing groups in other health and environment transport classes where the GHS classification and criteria may not provide the existing or desired distribution of PGs for the transport sector.
  - (b) The emphasis placed in many jurisdictions on reducing animal testing and encouraging alternatives as appropriate and valid methods, particularly for skin corrosion.

### Action

13. The Joint Informal Correspondence Group is invited to indicate which option is the preferred way forward, and to comment on the questions and details in Annexes 2 to 5.

14. The expert from the United Kingdom will develop and refine the preferred option in the light of the discussion on 3 December 2013 and produce a further information document for discussion at a meeting of the Joint Group in June/July 2014 with a view to submitting a working document for agreement of both TDG and GHS sub-committees in December 2014.

### Annex 1

# Agenda for meeting of the Joint TDG/GHS informal correspondence group on corrosivity criteria<sup>1</sup>

to be held at the Palais des Nations (Room XII), Geneva, on Tuesday 3 December 2013 at  $14{:}30^2$ 

### 1. Welcome and introduction

### 2. Discussion of informal documents:

INF.29 (TDG) – INF.11 (GHS) (United Kingdom)	Consistency of classification criteria in the UN Model Regulations and in the GHS: Options for a way forward
INF.22 (TDG) – INF.10 (GHS) (Australia)	Comment on INF.42 (TDG, 43rd session) – INF.11 (GHS, 25th session)
INF.32 (TDG) – INF.12 (GHS) (CEFIC)	Harmonisation corrosivity criteria
INF.34 (TDG) – INF.13 (GHS) (CEFIC)	Skin corrosive substances classification

Any other documents submitted prior to the meeting

- 3. Any other business
- 4. Next steps

### Summary of documents submitted up July 2013

### 21st GHS Session/39th TDG Session (June 2011):

• INF.6 (GHS) – INF.14 (TDG) - (United Kingdom) Update on work of the informal joint correspondence group on corrosivity criteria

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### 22nd GHS Session/40th TDG Session (December 2011):

- **INF.12 (GHS) INF.9 (TDG)** (ICCA) Harmonization of classification criteria for transport with the classification criteria of the GHS for substances and mixtures corrosive to skin
- **INF.13 (GHS) INF.10 (TDG)** (ICCA) Harmonization of classification criteria for transport with the classification criteria of the GHS for substances and mixtures corrosive to skin

 $<sup>^1\,</sup>$  For the terms of reference of the joint working group refer to ST/SG/AC.10/C.4/48, Annex IV , item 1 (h).

<sup>&</sup>lt;sup>2</sup> Refer to the provisional agenda for the 26th session of the GHS Sub-Committee, ST/SG/AC.10/C.4/51, -51/Add.1 and INF.9.

- **INF.17** (**GHS**) **INF.30** (**TDG**) (ICPP) Harmonization of classification criteria for transport with the classification criteria of the GHS for substances and mixtures corrosive to skin
- INF.18 (GHS) INF.33 (TDG) (United Kingdom) Work of the joint correspondence group on corrosivity criteria
- INF.18/Add.1 (GHS) INF.33/Add.1 (TDG) (United Kingdom) Work of the joint correspondence group on corrosivity criteria: agenda for the meeting and additional information

#### 23rd GHS Session/41st TDG Session (July 2012):

- INF.11 (GHS) INF.27 (TDG) (CEFIC) Harmonisation of the skin corrosion classification criteria in the UN Model Regulations with those in GHS
- **INF.28** (**TDG**) (CEFIC) Adoption of expert judgement and weight of evidence procedures into the Model Regulations
- **INF.14** (**GHS**) **INF.41** (**TDG**) (United Kingdom) Update on the work of the joint informal correspondence group on corrosivity classification
- **INF.18** (**GHS**) **INF.53** (**TDG**) (United Kingdom) Contribution to the work of the joint informal correspondence group on corrosivity classification approaches to classifying corrosive mixtures under Class 8

#### 24th GHS Session/42nd TDG Session (December 2012)

- **INF.8** (GHS) –**INF.16** (TDG) (CEFIC) Harmonisation of the skin corrosion classification criteria in the Model Regulations with those in GHS
- **INF.12 (GHS) INF.25 (TDG)** (CEFIC) Corrections to INF.8 (GHS) INF.16 (TDG) Harmonisation of the skin corrosion classification criteria in the Model Regulations with those in GHS
- **INF.17** (**GHS**) **INF.37** (**TDG**) (Netherlands) Implementation of GHS corrosivity criteria in the Model Regulations

#### 25th GHS Session/43rd TDG Session (July 2013)

- INF.9 (GHS) INF.26 (TDG) and ADD1 (CEFIC) Harmonisation of the skin corrosion classification criteria in the UN Model Regulations on the Transport of Dangerous Goods with those in GHS
- INF.11(GHS) INF.42 (TDG) (United Kingdom) Consistency of classification criteria in the UN Model Regulations and in the GHS: Options for a way forward and agenda for the meeting of joint working group on corrosivity criteria

### Annex 2 (Options 2 and 5)

### **"CHAPTER 3.2**

### SKIN CORROSION/IRRITATION

### **3.2.1 Definitions and general considerations**

3.2.1.1 *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<sup>1</sup>. 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.

*Skin irritation* is the production of reversible damage to the skin following the application of a test substance for up to 4 hours<sup>1</sup>.

3.2.1.2 In a tiered approach, emphasis should 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** Classification criteria for substances

Substances can be allocated to one of the following three categories within this hazard class:

(a) Category 1 (skin corrosion)

This category may be further divided into up to three sub categories (1A, 1B and 1C) which can be used by those authorities requiring more than one designation for corrosivity (see Table 3.2.1)

- (b) Category 2 (skin irritation) (see Table 3.2.2)
- (c) Category 3 (mild skin irritation)

This category is available for those authorities (e.g. pesticides) that want to have more than one skin irritation category (see Table 3.2.2).

<sup>&</sup>lt;sup>1</sup> This is a working definition for the purpose of this document.

### 3.2.2.1 Classification based on standard animal test data

### 3.2.2.1.1 Skin corrosion

3.2.2.1.1.1 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 and observations up to 14 days.

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 For those authorities wanting more than one designation for skin corrosion, up to three sub categories are provided within the corrosion category (Category 1, see Table 3.2.1): sub category 1A, where corrosive responses are noted following up to 3 minutes exposure and up to 1 hour observation; sub-category 1B, 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, where corrosive responses occur after exposures greater than 1 hour and up to 4 hours and observations up to 14 days.

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

#### Table 3.2.1: Skin corrosion category and sub-categories<sup>a</sup>

<sup>a</sup> The use of human data is discussed in 3.2.2.2 and in chapters 1.1 (par. 1.1.2.5 (c)) and 1.3 (par. 1.3.2.4.7).

3.2.2.1.2	Skin irritation
	(no change and not reproduced here)
3.2.2.2	Classification in a tiered approach
	(no change and not reproduced here)
3.2.3	Classification criteria for mixtures
3.2.3.1	Classification of mixtures when data are available for the complete mixture
	(no change and not reproduced here)
3.2.3.2 principles	Classification of mixtures when data are not available for the complete mixture: bridging

## **3.2.3.3** Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

3.2.3.3.1 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  $\geq 1\%$  (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 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.

3.2.3.3.4 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 3.2.3.3.2 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 be used as classification criteria (see 3.2.3.1.2) since pH will be a better indicator of corrosion than the concentration limits in Table 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 be classified as skin corrosion Category 1 if it contains  $\geq$  1% of a corrosive ingredient and as skin irritation Category 2 or Category 3 when it contains  $\geq$  3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table 3.2.3 does not apply is summarized in Table 3.2.4 below.

3.2.3.3.5 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 3.2.3 and 3.2.4. In these cases the mixture could 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 3.2.3 and 3.2.4, testing of the mixture may be considered. In those cases the tiered weight of evidence approach should be applied as described in 3.2.3 and illustrated in Figure 3.2.1.

3.2.3.3.6 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 be classified accordingly (see also *Classification of hazardous substances and mixtures – Use of cut-off values/Concentration limits* (1.3.3.2)).

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:			
	Skin corrosive	Skin irritant		
	Category 1 (see note below)	Category 2	Category 3	
Skin Category 1	≥ 5%	$\geq 1\%$ but < 5%		
Skin Category 2		≥ 10%	$\geq 1\%$ but < 10%	
Skin Category 3			≥ 10%	
(10 × Skin Category 1) + Skin Category 2		≥ 10%	$\geq 1\%$ but < 10%	
(10 × Skin Category 1) + Skin Category 2 + Skin Category 3			≥ 10%	

 Table 3.2.3: Concentration of ingredients of a mixture classified as skin Category 1, 2 or 3 that would trigger classification of the mixture as hazardous to skin (Category 1, 2 or 3)

**NOTE:** Where the sub categories of skin Category 1 (corrosive) are used, the sum of all ingredients of a mixture classified as sub-category 1A, 1B or 1C respectively, should each be  $\geq 5\%$  in order to classify the mixture as either skin sub-category 1A, 1B or 1C. Where the sum of 1A ingredients is <5% but the sum of 1A+1B ingredients is  $\geq 5\%$ , the mixture should be classified as sub-category 1B. Similarly, where the sum of 1A + 1B ingredients is <5% but the sum of 1A + 1B ingredients is <5% but the sum of 1A + 1B ingredients is <5% but the sum of 1A + 1B ingredients is <5% but the sum of 1A + 1B + 1C ingredients is  $\geq 5\%$  the mixture should be classified as sub-category 1 without sub-category 1 without sub-categories as categories as Categories as a categories of the sum of all ingredients in a mixture is classified as Categories 1 without sub-categories as bound be classified as categories as a categories of the sum of all ingredients is  $\geq 5\%$ .

## Table 3.2.4: Concentration of ingredients of a mixture when the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin

Ingredient:	Concentration:	Mixture classified as: Skin
Acid with $pH \le 2$	$\geq 1\%$	Category 1
Base with $pH \ge 11.5$	≥ 1%	Category 1
Other corrosive (Category 1) ingredient	$\geq 1\%$	Category 1
Other irritant (Category 2/3) ingredient, including acids and bases	≥ 3%	Category 2/3

### 3.2.4 Hazard communication

General and specific considerations concerning labelling requirements are provided in *Hazard communication: Labelling* (Chapter 1.4). Annex 1 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority. The table below presents specific label elements for substances and mixtures that are classified as irritating or corrosive to the skin based on the criteria set forth in this chapter.

	Category 1	Category 2	Category 3
	<del>1 A</del>		
Symbol	Corrosion	Exclamation mark	No symbol
Signal word	Danger	Warning	Warning
Hazard statement	Causes severe skin burns and eye damage	Causes skin irritation	Causes mild skin irritation

### Table 3.2.5: Label elements for skin corrosion/irritation

### 3.2.5 Decision logics and guidance

(Not considered at this stage)

### Annex 3 (Option 2)

### **"CHAPTER 2.8**

### **CLASS 8 - CORROSIVE SUBSTANCES**

#### 2.8.1 Definition

*Class 8 substances (corrosive substances)* are substances which, by chemical action, [lead to 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 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.

(*Comment 1*: in transport "substance" means "substance and mixture". Some consequential changes made throughout the Annex)

(Comment 2: Text between brackets inserted to align definitions in transport and GHS)

### 2.8.2 Corrosive to skin

2.8.2.1 In a tiered approach, emphasis [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 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 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.

(Question 1: "Should" in the GHS replaced here and elsewhere by "shall" in the Model Regulations. Is this correct?)

#### 2.8.3 Assignment of packing groups

2.8.3.1 Substances of Class 8 are divided among the three packing groups according to their degree of hazard in transport as follows:

(a) *Packing group I:* Very dangerous [substances];

(Comment 3: In 2.8.2.1 currently "substances and preparations")

- (b) *Packing group II*: Substances presenting medium danger;
- (c) *Packing group III*: Substances presenting minor danger.

2.8.3.2 Substances are Class 8 when they produce 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 and observations up to 14 days. Within Class 8 packing groups are assigned in accordance with Table 2.8.1 where animal data are available and within the tiered approach as set out in 2.8.3.1 and in Figure 2.8.1.

	Exposure Time	Observation Period	Effect
Class 8 PG I	$\leq$ 3 min	$\leq 60 \min$	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure, and the substance has one of the properties in Note 2 to this table
Class 8 PG II	$\leq 3 \min$ > 3 min $\leq 1 h$	$\leq 60 \min$ $\leq 14 d$	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure
Class 8 PG III	$> 1 h \leq 4 h$	≤ 14 d	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure

### Table 2.8.1 – Corrosive to skin – Class 8 and assignment of packing group

### Notes to Table 2.8.1

**NOTE 1:** In assigning the packing group to a substance and in line with the tiered approach, 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<sup>1</sup> or 435<sup>2</sup>. A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430<sup>3</sup> or 431<sup>4</sup> may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

(Comment 4: Note 1, previously 2.8.2.4. Update to align with note (d) to Fig 2.8.1)

**NOTE 2:** Packing group I [shall] be assigned where the substance also has <u>one</u> of the following properties:

- (a) Inhalation risk (see Note 3)
- (b) Reactivity with water (including the formation of dangerous decomposition products)

(Question 2: Text of (a) and (b) taken from the first sentence of 2.8.2.2. Are (a) and (b) incorporated in (c) to (g) below?)

- (c) Sufficiently volatility to evolve corrosive vapours and/or produce toxic gases when decomposed by very high temperatures;
- (d) Additional systemic toxic properties;
- (e) Potential to becoming corrosive after having reacted with water, or with moisture in the air, accompanied by the liberation of corrosive gases. Such gases usually become visible as fumes in the air;
- (f) Potential to evolve considerable heat in reaction with water leading to splattering of material
- (g) Potential to evolve considerable heat in reaction with organic chemicals, including wood, paper, fibres, some cushioning materials and certain fats and oils.

(*Comment 5*: *Text of* (*c*) *to* (*g*) *taken from CEFIC documents INF16* ( $42^{nd}$  TDG) – *INF8* ( $24^{th}$  GHS)

<sup>&</sup>lt;sup>1</sup> OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2002.

<sup>&</sup>lt;sup>2</sup> OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006.

<sup>&</sup>lt;sup>3</sup> OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.

<sup>&</sup>lt;sup>4</sup> OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2004.

**NOTE 3**: A substance 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).

(Question 3: Note 3, previously 2.8.2.3. Is this ok as a note to the Table? Is it related to (d) above? "... meeting the criteria of Class 8 ... shall be allocated to Class 8"?)

**NOTE 4**: Liquids, and solids which may become liquid during transport, which are judged not to cause corrosive responses to skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.4.

(*Comment 6*: *Text of Note 4 taken from the last sentence of 2.8.2.2*)

2.8.3.3 Assignment of packing groups to substances listed in the Dangerous Goods List in Chapter 3.2 has been made on the basis of human experience taking into account the criteria in Table 2.8.1 including, for assignment of packing group I, the additional criteria in Note 2 to this table.

2.8.3.4 Where a substance is not listed in the Dangerous Goods List, a tiered approach to the evaluation of initial information shall be considered, where applicable (Figure 2.8.1), recognizing that not all elements may be relevant.

2.8.3.5 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.

2.8.3.6 Acute dermal toxicity data may be used for classification. If a substance is highly toxic by the dermal route, a skin corrosion 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 in acute toxicity studies and are observed up through the limit dose, these data may be used for classification, provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive when moistened or in contact with moist skin or mucous membranes.

2.8.3.7 In vitro alternatives that have been validated and accepted [shall] be used to make classification decisions.

2.8.3.8 Likewise, pH extremes like  $\leq 2$  and  $\geq 11.5$  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 [shall] be considered Class 8 if it has a pH  $\leq 2$  or a pH  $\geq 11.5$ . However, if consideration of acid/alkaline reserve 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.

## (Question 4: pH ok for classifying as Class 8, but applicability of pH in assigning PG for transport? See INF.26 (43<sup>rd</sup> TDG) – INF.9 (25<sup>th</sup> GHS))

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

### (Question 5: Applicability in transport for classifying as Class 8 and/or for assigning PG?)

2.8.3.10 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 2.8.3.4),

#### UN/SCETDG/44/INF. 29 UN/SCEGHS/26/INF. 11

consideration 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.

### Figure 2.8.1: Tiered evaluation for skin corrosion

(Comment 7: Original steps numbers in the table in GHS Chapter 3.2 retained for now to show changes)

<u>Step</u>	Parameter_		Finding		<u>Conclusion</u>
<b>1a:</b>	Existing human or animal skin corrosion data <sup>a</sup> ↓ Not corrosive/No data	<b>→</b>	Skin corrosive	<b>→</b>	Classify as <b>Class 8</b> <sup>b</sup>
1c:	<ul> <li>✓</li> <li>Existing human or animal skin corrosion data <sup>a</sup></li> <li>✓</li> <li>No/Insufficient data</li> <li>✓</li> </ul>	<b>→</b>	Not a skin corrosive	<b>→</b>	Not classified
2:	Other, existing skin data in animals <sup>c</sup> ↓ No/Insufficient data ↓	<b>→</b>	Yes; other existing data showing that substance may cause skin corrosion	→	May be deemed to be Class 8 <sup>b</sup>
3:	Existing <i>ex vivo/in vitro</i> data <sup>d</sup> No/Insufficient data/Negative response V	<b>→</b>	Positive: Skin corrosive	<b>→</b>	Classify as <b>Class 8</b> <sup>b</sup>
4:	pH-based assessment (with consideration of acid/alkaline reserve of the chemical) <sup>e</sup> ↓ Not pH extreme, no pH data or extreme pH with data showing low/no acid/alkaline reserve ↓	<b>→</b>	$pH \le 2 \text{ or } \ge 11.5$ with high acid/alkaline reserve or no data for acid/alkaline reserve	→	Classify as <b>Class 8</b>
5:	Validated Structure Activity Relationship (SAR) methods ↓ No/Insufficient data ↓	→	Skin corrosive	<b>→</b>	Deemed to be Class 8 <sup>b</sup>
6:	Consideration of the total weight of evidence <sup>f</sup>	<b>→</b>	Skin corrosive	<b>→</b>	Deemed to be Class 8 <sup>b</sup>
7:	Not classified				

<sup>(</sup>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 packing group;
- (c) All existing animal data [shall] be carefully reviewed to determine if sufficient skin corrosion evidence is available. In evaluating such data, however, the reviewer should 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 be assessed. Examples of internationally accepted validated test methods for skin corrosion include OECD Test Guidelines 430 (Transcutaneous Electrical Resistance Test (TER), 431(Human Skin Model Test), and 435 (Membrane Barrier 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 [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 [shall] be exercised prior to making such a determination. Negative results from applicable validated skin corrosion in vitro tests are considered in the total weight of evidence evaluation.

## **2.8.3.11** Classification of [mixtures] and assignment of packing group when data are not available for the complete [mixture]: bridging principles

#### (Comment 8: "Mixtures": need appropriate term for transport)

(Question 6: Do these bridging principles apply to assignment of PG I where assignment is based both on a health hazard (skin corrosion) and the presence of one of the other (generally non-health) properties in (a) to (g) of Note 2 to Table 2.8.1? If yes, how should the bridging principles be amended in these circumstances? If no, what are the implications?)

2.8.3.12 Where the mixture itself 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 characterize the hazards of the mixture, these data [shall] 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.

2.8.3.13 *Dilution* 

If a tested mixture is diluted with a diluent which is also Class 8 and which is not expected to affect the skin corrosivity of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture. Alternatively, the method explained in 2.8.3.20 to 2.8.3.22 could be applied.

2.8.3.14 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.

### 2.8.3.15 *Concentration of mixtures*

If a tested mixture classified in the highest packing group is concentrated the more concentrated untested mixture [shall] be classified in the highest packing group without additional testing.

#### UN/SCETDG/44/INF. 29 UN/SCEGHS/26/INF. 11

### 2.8.3.16 Interpolation within one hazard

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are Class 8, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be Class 8.

(Comment 9: Note "toxicologically" - see Question 6)

2.8.3.17 *Substantially similar mixtures* 

Given the following:

- (a) Two mixtures: (i) A + B; (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on skin corrosion for A and C are available and substantially equivalent, i.e. they are Class 8 and are not expected to affect the skin corrosion potential of B.

If mixture (i) or (ii) is already classified as Class 8 based on test data, then the other mixture can also be classified as Class 8.

### 2.8.3.18 Aerosols

### (Question 7: Aerosols, applicability to transport?)

An aerosol form of a mixture may be classified as Class 8 if the tested non-aerosolized form of the mixture is Class 8 and provided that the added propellant does not affect the skin corrosion properties of the mixture.

## **2.8.3.19** Classification of [mixtures] and assignment of packing groups when data are available for all ingredients or only for some ingredients of the [mixture]

(*Comment 10*: The criteria in section this (2.8.3.19) and the following section are drawn from the CEFIC paper INF.16 ( $42^{nd}$  TDG)–INF.8 ( $24^{th}$  GHS)

2.8.3.20 In order to make use of all the available data for purposes of classifying the skin corrosion hazards of mixtures and assigning packing groups, 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  $\geq 1\%$  (w/w for solids, liquids, dusts, mists and vapours and v/v for gases), unless there is a presumption that an ingredient present in a concentration < 1% can still be relevant for classifying the mixture for skin corrosion.

2.8.3.21 In general, the approach to classification of mixtures as corrosive 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 ingredient contributes to the overall corrosive properties of the mixture in proportion to its concentration. This is applied as appropriate in the tiered approach. The mixture is classified as Class 8 when the sum of the concentrations of such ingredients is  $\geq 5\%$ .

(Question 8: Can additivity be assumed for assignment of PG I to mixtures when PG I for the ingredient substances is based on a combination of skin corrosion and other (generally) non-toxicological properties as in Note 2 to Table 2.8.1?)

2.8.3.22 Packing group I is assigned where:

- (a) The mixture contains an ingredient assigned packing group I at a concentration  $\geq$  5%; or
- (b) The mixture contains more than one ingredient assigned packing group I at concentrations < 5%, and the sum of the concentrations of these ingredients is  $\ge 5\%$ ; or
- (c) The total weight of evidence supports the assignment of packing group I.

Packing group II is assigned where the criteria in (a) to (c) above are not met and

- (d) The mixture contains an ingredient assigned packing group II at a concentration  $\geq$  5%; or
- (e) The sum of the concentrations of ingredients assigned packing group I is < 5%, but the sum of the concentrations of ingredients assigned packing groups I and II is  $\geq$  5%
- (f) The total weight of evidence supports the assignment of packing group II.

Packing group III is assigned where the criteria in (a) to (f) above are not met and:

- (g) The mixture contains an ingredient assigned packing group III at a concentration  $\geq$  5%; or
- (h) The sum of the concentrations of ingredients assigned packing groups I and II is < 5%, but the sum of the concentrations of ingredients assigned packing groups I, II and III is  $\ge 5\%$ ; or
- (i) The total weight of evidence supports the assignment of packing group III.

2.8.3.23 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 2.8.3.20 to 2.8.3.22 might not work given that many such substances are corrosive at concentrations < 5%. For mixtures containing strong acids or bases the pH [shall] be used as classification criteria since pH will be a better indicator of corrosion than the concentration limit of 5%.

### (Question 9: Applicability of pH in assigning PG for transport? See INF26 (43<sup>rd</sup> TDG)–INF.9 (25<sup>th</sup> GHS)

A mixture containing corrosive ingredients that cannot be classified based on the additivity approach due to chemical characteristics that make this approach unworkable, [shall] be classified as Class 8 if it contains  $\geq 1\%$  of a corrosive ingredient. In these circumstances packing group II is assigned by default unless the criteria in 2.8.2.24 apply.

- 2.8.3.24 The default assignment of packing group II in 2.8.3.23 is not applied where:
  - (a) An ingredient in the mixture at a concentration  $\geq$  5% is assigned to packing group I in the Dangerous Good List in Chapter 3.2, when the mixture [shall] be assigned packing group I; or
  - (b) The criteria in Note 2 to Table 2.8.1 apply, in which case packing group I is assigned; or
  - (c) The total weight or evidence supports either assignment of packing group 1 or packing group III.

#### UN/SCETDG/44/INF. 29 UN/SCEGHS/26/INF. 11

2.8.3.25

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The criteria in 2.8.3.20 to 2.8.3.24 are summarised in Table 2.8.2.

Ingredient(s) classified as Class 8:	<b>Concentration:</b>	Mixture classified as <sup>a</sup>
Corrosivity effects additive		
Sum of ingredients assigned PG I	≥ 5%	Class 8 PG I
Sum of ingredients assigned PG II	≥ 5%	Class 8, PG II
Sum of ingredients assigned PG I; and sum of the ingredients assigned PG I and II	< 5% ≥ 5%	Class 8, PG II
Sum of ingredients assigned PG I and II; and sum of the ingredients assigned PG I, II and III	< 5% ≥ 5%	Class 8, PG III
Acid with $pH \le 2$ or base with $pH \ge 11.5$	≥1%	Class 8, PG II <sup>b</sup>
Corrosivity effects not additive		
Other Class 8 ingredients	≥1%	Class 8, PG II <sup>b</sup>

### **Table 2.8.2**

Where appropriate packing Groups I, II and III can also be assigned on the basis of a total weight of evidence approach.

<sup>b</sup> Unless the criteria in 2.8.3.24 apply.

2.8.3.26 On occasion, reliable data may show that the skin corrosion of an ingredient will not be evident when present at a level above the concentrations in Table 2.8.2. In these cases the mixture could be classified according to those data and packing groups assigned accordingly. On occasion, when it is expected that the skin corrosion of an ingredient will not be evident when present at a level above these concentrations, testing of the mixture may be considered. In those cases the tiered weight of evidence approach should be applied as described in 2.8.2.11 to 2.8.2.25 and illustrated in Figure 2.8.1.

2.8.3.27 If there are data showing that (an) ingredient(s) may be corrosive to skin at a concentration of < 1%, the mixture should be classified and packing group assigned accordingly.

#### 2.8.4 Corrosive to metals

2.8.4.1 Substances are Class 8 where the corrosion rate on either steel or aluminium surfaces exceeds 6.25 mm a year at a test temperature of  $55^{\circ}$ C when tested on both materials.

2.8.4.2 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. 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 Liquids, and solids which may become liquid during transport, which are judged not to be corrosive to skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.4.1 and 2.8.4.2 above.

2.8.4.4 Packing Group III is assigned in accordance with Table 2.8.3 below

**Table 2.8.3** 

Packing group	Effect
III	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

### Annex 4 (Option 5)

### **"CHAPTER 2.8**

### **CLASS 8 - CORROSIVE SUBSTANCES**

### 2.8.1 Definition

2.8.1.1 *Class 8 (corrosive) substances* are substances and mixtures which, by chemical action, [lead to 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 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.

(*Comment 11*: in transport "substance" means "substance and mixture". Some consequential changes made throughout the Annex)

(Comment 12: Text between brackets inserted to align definitions in transport and GHS)

### 2.8.2 Corrosive to skin

2.8.2.1 In a tiered approach, emphasis [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 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 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.

(Question 10: "Should" in the GHS replaced here and elsewhere by "shall" in the Model Regulations. Is this correct?)

2.8.2.2 Substances are Class 8 when they produce 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 and observations up to 14 days.

Table 2.8.1: Class 8 skin corrosion

	Criteria
Category 1	Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure $\leq 4$ h and observations $\leq 14$ days

2.8.2.3 A tiered approach to the evaluation of initial information [shall] be considered, where applicable (Figure 2.8.1), recognizing that not all elements may be relevant.

2.8.2.4 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.

2.8.2.5 Acute dermal toxicity data may be used for classification. If a substance is highly toxic by the dermal route, a skin corrosion 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 in acute toxicity studies and are observed up through the limit dose, these data may be used for

classification, provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive when moistened or in contact with moist skin or mucous membranes.

2.8.2.6 In vitro alternatives that have been validated and accepted [shall] be used to make classification decisions.

2.8.2.7 Likewise, pH extremes like  $\leq 2$  and  $\geq 11.5$  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 Class 8 if it has a pH  $\leq 2$  or a pH  $\geq 11.5$ . However, if consideration of acid/alkaline reserve suggests the substance or 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.

### (Question 11: pH ok for classifying as Class 8?)

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

### (Question 12: Ok for classifying as Class 8?)

2.8.2.9 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 2.8.2.3), consideration should 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.

### Figure 2.8.1: Tiered evaluation for skin corrosion

(Comment 13: Original steps numbers in the table in GHS Chapter 3.2 retained for now to show changes)

<u>Step</u>	Parameter	Finding	<u>Conclusion</u>
1a:	Existing human or animal skin corrosion data <sup>a</sup> ↓ Not corrosive/No data ↓	Skin corrosive →	Classify as <b>Class 8</b>
1c:	Existing human or animal skin corrosion data <sup>a</sup> ↓ No/Insufficient data ↓	Not a skin corrosive →	Not classified
2:	Other, existing skin data in animals <sup>c</sup> → ↓ No/Insufficient data	Yes; other existing data showing that substance may cause skin corrosion	May be deemed to be Class 8
3:	Existing <i>ex vivo/in vitro</i> data <sup>d</sup> → ↓ No/Insufficient data/Negative response ↓	Positive: Skin corrosive →	Classify as Class 8

### Figure 2.8.1: Tiered evaluation for skin corrosion

(*Comment 13:* Original steps numbers in the table in GHS Chapter 3.2 retained for now to show changes)

<u>Step</u>	<u>Parameter</u>	Finding	<u>Conclusion</u>
4:	<ul> <li>pH-based assessment (with consideration of acid/alkaline reserve of the chemical) <sup>e</sup></li> <li>✓</li> <li>Not pH extreme, no pH data or extreme pH with data showing low/no acid/alkaline reserve</li> <li>✓</li> </ul>	$pH \le 2 \text{ or } \ge 11.5 \text{ with high}$ acid/alkaline reserve or no data for acid/alkaline reserve	Classify as <b>Class 8</b>
5:	Validated Structure Activity Relationship (SAR) methods ↓ No/Insufficient data ↓	Skin corrosive →	Deemed to be Class 8
6:	Consideration of the total weight of → evidence <sup>f</sup> →	Skin corrosive →	Deemed to be Class 8
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;
- (c) All existing animal data [shall] be carefully reviewed to determine if sufficient skin corrosion evidence is available. In evaluating such data, however, the reviewer should 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 [shall] be assessed. Examples of internationally accepted validated test methods for skin corrosion include OECD Test Guidelines 430 (Transcutaneous Electrical Resistance Test (TER), 431(Human Skin Model Test), and 435 (Membrane Barrier 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 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 be exercised prior to making such a determination. Negative results from applicable validated skin corrosion in vitro tests are considered in the total weight of evidence evaluation.

## **2.8.2.10** Classification of [mixtures] when data are not available for the complete [mixture]: bridging principles

(*Comment 14*: "*Mixtures*" = *Need appropriate term for transport*)

2.8.2.11 Where the mixture itself 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 characterize the hazards of the mixture, these data should 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.

### 2.8.2.12 *Dilution*

If a tested mixture is diluted with a diluent which is also Class 8 and which is not expected to affect the skin corrosivity of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture. Alternatively, the method explained in 2.8.2.16 to 2.8.2.20 could be applied.

#### 2.8.2.13 *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.

#### 2.8.2.14 *Concentration of mixtures*

If a tested mixture classified Class 8 skin corrosive is concentrated the more concentrated untested mixture [shall] be classified as Class 8 skin corrosive without additional testing.

#### 2.8.2.15 Interpolation within one hazard

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are Class 8, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be Class 8.

2.8.2.16 *Substantially similar mixtures* 

Given the following:

(a) Two mixtures: (i) A + B;

(ii) C + B;

- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on skin corrosion for A and C are available and substantially equivalent, i.e. they are Class 8 and are not expected to affect the skin corrosion potential of B.

If mixture (i) or (ii) is already classified as Class 8 based on test data, then the other mixture can also be classified as Class 8.

### 2.8.2.17 Aerosols

#### (Question 13: Aerosols: applicability to transport?)

An aerosol form of a mixture may be classified as Class 8 if the tested non-aerosolized form of the mixture is Class 8 and provided that the added propellant does not affect the skin corrosion properties of the mixture.

## **2.8.2.18** Classification of [mixtures] when data are available for all ingredients or only for some ingredients of the [mixture]

2.8.2.19 In order to make use of all the available data for purposes of classifying the skin corrosion 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  $\geq 1\%$  (w/w for solids, liquids, dusts, mists and vapours and v/v for gases), unless there is a presumption that an ingredient present in a concentration < 1% can still be relevant for classifying the mixture for skin corrosion.

2.8.2.20 In general, the approach to classification of mixtures as corrosive 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 ingredient contributes to the overall corrosive properties of the mixture in proportion to its concentration. This is applied as appropriate in the tiered approach. The mixture is classified as Class 8 when the sum of the concentrations of such ingredients is  $\geq 5\%$ .

2.8.2.21 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 2.8.1.19 and 2.8.1.20 might not work given that many such substances are corrosive at concentrations < 5%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limit of 5%. A mixture containing corrosive ingredients that cannot be classified based on the additivity approach due to chemical characteristics that make this approach unworkable, should be classified as Class 8 if it contains  $\ge 1\%$  of a corrosive ingredient.

### 2.8.2.22 The criteria in 2.8.1.19 to 2.8.1.21 are summarised in Table 2.8.2.

Ingredient classified as Class 8:	Concentration:	Mixture classified as
Corrosivity effects additive	≥ 5%	Class 8
Acid with $pH \le 2$ or base with $pH \ge 11.5$	$\geq 1\%$	Class 8
Corrosivity effects not additive – other Class 8 ingredients	≥1%	Class 8

### **Table 2.8.2**

2.8.2.23 On occasion, reliable data may show that the skin corrosion of an ingredient will not be evident when present at a level above the concentrations in Table 2.8.2. In these cases the mixture could be classified according to those data. On occasion, when it is expected that the skin corrosion of an ingredient will not be evident when present at a level above these concentrations, testing of the mixture may be considered. In those cases the tiered weight of evidence approach should be applied as described in 2.8.2.1 and illustrated in Figure 2.8.1.

2.8.2.24 If there are data showing that (an) ingredient(s) may be corrosive to skin at a concentration of < 1%, the mixture should be classified accordingly.

### 2.8.3 Corrosive to metals

2.8.3.1 Substances are Class 8 where the corrosion rate on either steel or aluminium surfaces exceeds 6.25 mm a year at a test temperature of  $55^{\circ}$ C when tested on both materials.

2.8.3.2 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. 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.

2.8.3.3 Liquids, and solids which may become liquid during transport, which are judged not to be corrosive to skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.3.1 and 2.8.3.2 above.

### 2.8.4 Assignment of packing groups

(*Comment 15*: Text for this section drawn from CEFIC paper INF16(42<sup>nd</sup> TDG)– INF.8 (24<sup>th</sup> GHS)

(Comment 16: Under Option 5 assignment of PG is a transport condition and does not affect classification as Class 8 skin corrosion. In practice, therefore, the transport sector is free to specify whatever criteria it considers appropriate here to secure the required distribution of PG I, II and III. The draft criteria below do not refer to the alternative methods for classification as skin corrosive.)

2.8.4.1 Substances of Class 8 are assigned three packing groups according to their degree of hazard and risk in transport as follows:

(a) *Packing group I:* Very dangerous [substances];

In 2.8.2.1 currently "substances and preparations")

(Comment 17:

- (b) *Packing group II*: Substances presenting medium danger;
- (c) Packing group III: Substances presenting minor danger.

2.8.4.2 Assignment of packing groups to substances listed in the Dangerous Goods List in Chapter 3.2 has been made on the basis of experience taking into account the criteria in Table 2.8.3.

2.8.4.3 Where the necessary data are available, other substances, including mixtures, [shall] be assigned packing groups on the basis of the criteria in Table 2.8.3.

Packing Group	Exposure Time	Observation Period	Effect
Ι	$\leq$ 3 min	$\leq$ 60 min	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure and the substance has one of the properties in Note 2 to this table.
П	$\leq 3 \min$ > 3 min $\leq 1 h$	$\leq 60 \min$ $\leq 14 d$	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure
III	$> 1 h \leq 4 h$	≤ 14 d	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one animal following exposure
III	-	-	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

Table	2.8.3
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**NOTE 1** In assigning the packing group to a substance, 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  $404^2$  or  $435^2$ . A substance 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.

### (Question 14: Note 1, previously 2.8.2.4. Update to align with note (d) to Fig 2.8.1?)

**NOTE 2:** Packing group I [shall] be assigned where the substance also has <u>one</u> of the following properties:

- (a) Inhalation risk (see Note 3)
- (b) Reactivity with water (including the formation of dangerous decomposition products)

## (Question 15: Text of (a) and (b) taken from the first sentence of 2.8.2.2. Are (a) and (b) incorporated in (c) to (g) below?)

- (c) Sufficiently volatility to evolve corrosive vapours and/or produce toxic gases when decomposed by very high temperatures;
- (d) Additional systemic toxic properties;
- (e) Potential to becoming corrosive after having reacted with water, or with moisture in the air, accompanied by the liberation of corrosive gases. Such gases usually become visible as fumes in the air;
- (f) Potential to evolve considerable heat in reaction with water leading to splattering of material
- (g) Potential to evolve considerable heat in reaction with organic chemicals, including wood, paper, fibres, some cushioning materials and certain fats and oils.

(*Comment 18:* Text of sub-paragraphs (c) to (g) taken from CEFIC paper INF.16 (42<sup>nd</sup>, TDG)– INF.8 (24<sup>th</sup>, GHS)

**NOTE 3:** A substance 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).

## (Question 16: Text of Note 3, previously 2.8.2.3. Is this ok as a note to the Table? Is it related to (d) above? "... meeting the criteria of Class 8 ... shall be allocated to Class 8"?)

2.8.4.4 Where the data on skin corrosion needed to apply the criteria in Table 2.8.3 are not available for Class 8 substances packing group II is assigned by default unless the criteria in 2.8.4.5 below apply.

- 2.8.4.5 Packing group I [shall] be assigned where:
  - (a) The substance contains an ingredient assigned packing group I in the Dangerous Goods List in Chapter 3.2 at a concentration  $\geq$  5%; or

<sup>&</sup>lt;sup>2</sup> OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2002.

<sup>&</sup>lt;sup>2</sup> OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006.

<sup>&</sup>lt;sup>3</sup> OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.

<sup>&</sup>lt;sup>4</sup> OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2004.

- (b) The substance contains an ingredient assigned packing group I in accordance with Table 2.8.3 above at a concentration  $\geq$  5%; or
- (c) The sum of the concentrations of ingredients assigned packing group I in accordance with (a) or (b) above is ≥ 5%;
- (d) The total weight of evidence supports the assignment of packing group I.

Packing group III is assigned where:

- (e) The sum of the concentrations of Class 8 ingredients in the mixture assigned packing group I or II is < 5%, but the sum of the concentrations of Class 8 ingredients assigned packing group III is  $\geq$  5%; or
- (f) The total weight of evidence supports the assignment of packing group III.

### Annex 5 (Option 6)

### CHAPTER 2.8

### **CLASS 8 - CORROSIVE SUBSTANCES**

### 2.8.1 Definition

2.8.1.1 *Class 8 (corrosive) substances* are substances which, by chemical action, [lead to 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 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.

(*Comment 19:* in transport 'substance' means 'substance and mixture'. Some consequential changes made throughout the Annex)

(Comment 20: Text into brackets inserted to align definitions in transport and GHS)

### 2.8.2 Corrosive to skin

### (Question 17: To what extent is the tiered approach appropriate under Option 6?)

2.8.2.1 Emphasis [shall] be placed upon existing and available human and animal data. Classification as Class 8 and assignment of packing group results directly when the data satisfy the criteria. Where these data are not available alternative methods including *in vitro* data, bridging principles, calculation methods based on additivity of corrosive effects, pH and methods where additivity is not considered to apply are used to classify as Class 8, and other rules are used to assign packing group.

(Question 18: "Should" in the GHS replaced here and elsewhere by "shall" in the Model Regulations. Is this correct?)

## 2.8.3 Classification as Class 8 and assignment of packing groups using existing human and animal data

2.8.3.1 Substances are Class 8 when they produce 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 and observations up to 14 days.

2.8.3.2 Substances of Class 8 are divided among the three packing groups according to their degree of hazard in transport as follows:

(a) *Packing group I:* Very dangerous substances;

(Comment 21: In 2.8.2.1 currently "substances and preparations")

- (b) *Packing group II*: Substances presenting medium danger;
- (c) *Packing group III*: Substances presenting minor danger.

2.8.3.3 Within Class 8 packing groups are assigned in accordance with Table 2.8.1.

2.8.3.4 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. In the absence of experience assignment of packing group shall be based on existing available data obtained from experiments in accordance with OECD Test Guideline  $404^{1}$ .

### (Comment 22: Text of 2.8.3.4 = Previously first part of 2.8.2.4)

2.8.3.5 Acute dermal toxicity data may be used for classification. If a substance is highly toxic by the dermal route, a skin corrosion 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 in acute toxicity studies and are observed up through the limit dose, these data may be used for classification, provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive when moistened or in contact with moist skin or mucous membranes.

### Table 2.8.1: Corrosive to skin - Class 8 and assignment of packing group

	Exposure time	Observation period	Effect
Class 8 PG I	$\leq$ 3 min	$\leq$ 60 min	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure
Class 8 PG II	$> 3 \min \le 1 h$	≤ 14 d	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure
Class 8 PG III	$> 1 h \leq 4 h$	≤ 14 d	Destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis in at least one tested animal following exposure

### Notes to Table 2.8.1

**NOTE 1:** A substance 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).

(Question 19: Text of Note 1 was previously 2.8.2.3. Is this ok as a note to the Table? "... meeting the criteria of Class 8 ... shall be allocated to Class 8"?)

**NOTE 2**: Liquids, and solids which may become liquid during transport, which are judged not to cause corrosive responses to skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.3.

### (Comment 23: Text of Note 2 taken from last sentence of 2.8.2.2)

2.8.3.6 Assignment of packing groups to substances listed in the Dangerous Goods List in Chapter 3.2 has been made on the basis of human experience taking into account the criteria in Table 2.8.1 [and including inhalation risk and reactivity with water (including the formation of dangerous decomposition products).]

<sup>&</sup>lt;sup>1</sup> *OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2002.* 

(Comment 24: Text between brackets taken from 2.8.2.2 first sentence)

(Question 20: For substances and mixtures not on the DGL Table 2.8.1 makes clear that the results of animal test data alone can give PG I? Although this is the position now, is the transport sector satisfied that in practice additional criteria to restrict assignment of PG I based only on animal test data are unnecessary?)

### 2.8.4 Classification as Class 8 using alternative methods and assignment of packing groups

2.8.4.1 <u>In vitro alternatives</u> that have been validated and accepted<sup>2</sup> [shall] be used to make classification decisions [and assign packing groups where possible]. Examples of internationally accepted validated test methods for skin corrosion include OECD Test Guidelines 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test) and 435 (Membrane Barrier Test Method). A substance 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.

### (Question 21: Is the third sentence needed?)

(Question 22: In vitro methods are improving and will continue to do so. 2.8.2.4 in the Orange book already allows PG assignment directly on the basis of OECD 435 – in vitro membrane barrier test method for skin corrosion. It also allows non-classification decisions to be made on the basis of OECD in vitro tests 430 and 431 (transcutaneous electrical resistance test and human skin model test). Should the results of in vitro tests be considered as equivalent to human or animal data for classification as Class 8, and for assignment of PGs where the tests can distinguish? If yes then in vitro is not an alternative test, and should be included in 2.8.3.)

2.8.4.2 Likewise, <u>pH extremes</u> like  $\leq 2$  and  $\geq 11.5$  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 [shall] be considered Class 8 if it has a pH  $\leq 2$  or a pH  $\geq 11.5$ . However, if consideration of acid/alkaline reserve suggests the substance or 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.

### (Question 23: pH ok for classifying as Class 8?

2.8.4.3 In some cases sufficient information may be available from <u>structurally related substances</u> to make classification decisions and assign packing group.

### (Question 24: Ok for classifying as Class 8 and / or for assigning PG?

2.8.4.4 Agreed <u>bridging principles</u> [shall] be used to classify mixtures when data are not available for the complete mixture but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture. 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.

<sup>&</sup>lt;sup>2</sup> Examples of internationally accepted validated test methods for skin corrosion include OECD Test Guidelines 430 (Transcutaneous Electrical Resistance Test (TER), 431(Human Skin Model Test), and 435 (Membrane Barrier Test Method).

<sup>&</sup>lt;sup>3</sup> OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.

<sup>&</sup>lt;sup>4</sup> OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2004.

(**Comment 25:** At this point in Option 6 the bridging principles can be applied for classification as Class 8 as the "additional factors" for PG I have not been included. However, if they are applied in 2.8.3 this may need to be reviewed.)

#### 2.8.4.5 Dilution

If a tested mixture is diluted with a diluent which is also Class 8 and which is not expected to affect the skin corrosivity of other ingredients, then the new diluted mixture may be classified as Class 8 and assigned the same packing group as the original tested mixture. Alternatively, the method explained in 2.8.4.11 to 2.8.4.17 could be applied.

#### 2.8.4.6 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.

2.8.4.7 Concentration of corrosive mixtures

If a tested mixture classified as Class 8 for skin corrosion is concentrated, the more concentrated untested mixture [shall] be classified as Class 8 without additional testing.

#### 2.8.4.8 Interpolation within one hazard

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are Class 8, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be Class 8.

#### (Comment 26: Note 'toxicologically' - see Question 20)

2.8.4.9 Substantially similar mixtures

Given the following:

- (a) Two mixtures: (i) A + B; (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on skin corrosion for A and C are available and substantially equivalent, i.e. they are Class 8 with the same packing group and are not expected to affect the skin corrosion potential of B.

If mixture (i) or (ii) is already classified as Class 8 based on test data, then the other mixture can also be classified as Class 8.

### 2.8.4.10 Aerosols

### (Question 25: Aerosols, applicability to transport?)

An aerosol form of a mixture may be classified as Class 8 if the tested non-aerosolized form of the mixture is Class 8, provided that the added propellant does not affect the skin corrosion properties of the mixture.

2.8.4.11 In order to make use of all the available data for purposes of classifying the skin corrosion hazards of mixtures, the following assumption has been made:

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

2.8.4.12 In general, the approach to classification of mixtures as corrosive to skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of <u>additivity</u>, such that each skin corrosive ingredient contributes to the overall corrosive properties of the mixture in proportion to its concentration. This is applied as appropriate in the tiered approach. The mixture is classified as Class 8 when the sum of the concentrations of such ingredients is  $\geq 5\%$ .

2.8.4.13 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 2.8.4.11 to 2.8.4.12 might not work given that many such substances are corrosive at concentrations < 5%. For mixtures containing strong acids or bases the pH [shall] be used as classification criteria since pH will be a better indicator of corrosion than the concentration limit of 5%. A mixture containing corrosive ingredients that cannot be classified based on the additivity approach due to chemical characteristics that make this approach unworkable, [shall] be classified as Class 8 if it contains  $\ge 1\%$  of a corrosive ingredient.

### 2.8.4.14 The criteria in 2.8.4.11 to 2.8.4.13 are summarised in Table 2.8.2.

Ingredient classified as Class 8:	Concentration:	Mixture classified as
Corrosivity effects additive	≥ 5%	Class 8
Acid with $pH \le 2$ or base with $pH \ge 11.5$	$\geq 1\%$	Class 8
Corrosivity effects not additive – other Class 8 ingredients	$\geq 1\%$	Class 8

### **Table 2.8.2**

2.8.4.15 On occasion, reliable data may show that the skin corrosion of an ingredient will not be evident when present at a level above the concentrations in Table 2.8.2. In these cases the mixture could be classified according to those data accordingly. On occasion, when it is expected that the skin corrosion of an ingredient will not be evident when present at a level above these concentrations, testing of the mixture may be considered.

2.8.4.16 If there are data showing that (an) ingredient(s) may be corrosive to skin at a concentration of < 1%, the mixture should be classified accordingly.

2.8.4.17 Where classification as Class 8 is based on alternative methods packing group II [shall] be assigned by default unless the criteria in 2.8.4.18 below apply:

2.8.4.18	Pack	king group I [shall] be assigned where:		
	(a)	The substance contains an ingredient assigned packing group I in the Dangerous Goods List in Chapter 3.2 at a concentration $\geq$ 5%; or		
	(b)	The substance contains an ingredient assigned packing group I in accordance with Table 2.8.1 at a concentration $\geq$ 5% and shows one of the following properties:		
		(i) Inhalation risk (see Note 3)		
		(ii) Reactivity with water (including the formation of dangerous decomposition products)		
(Question 26:	sub-pa	ragraphs (i) and (ii) taken from 2.8.2.2, first sentence. Are (i) and (ii) incorporated in (iii) to		
( <i>vii)</i> below:		<ul> <li>Sufficiently volatility to evolve corrosive vapours and/or produce toxic gases when decomposed by very high temperatures;</li> </ul>		
		(iv) Additional systemic toxic properties;		
		<ul> <li>Potential to becoming corrosive after having reacted with water, or with moisture in the air, accompanied by the liberation of corrosive gases. Such gases usually become visible as fumes in the air;</li> </ul>		
		(vi) Potential to evolve considerable heat in reaction with water leading to splattering of material		
		(vii) Potential to evolve considerable heat in reaction with organic chemicals, including wood, paper, fibres, some cushioning materials and certain fats and oils.		
(Comment 27:	sub-pa	ragraphs (iii) to (vii) taken from CEFIC paper INF.16 (42 <sup>nd</sup> TDG)– INF.8 (24 <sup>th</sup> GHS)		
	(c)	The sum of the concentrations of ingredients assigned packing group I under (a) or (b) above is $560$ .		
	(d)	$\geq$ 5%; The total weight of evidence supports the assignment of packing group I.		
	Pack	ting group III is assigned where:		
	(e)	The sum of the concentrations of Class 8 ingredients in the mixture assigned packing group I or II is < 5%, but the sum of the concentrations of Class 8 ingredients assigned packing group III is $> 5\%$ .		
	(f)	$15 \ge 5\%$ ; or The total weight of evidence supports the assignment of packing group III.		
2.8.5	Cori	rosive to metals		
2.8.5.1 6.25 mm a yea	Subs r at a tes	stances are Class 8 where the corrosion rate on either steel or aluminium surfaces exceeds st temperature of $55^{\circ}$ C when tested on both materials.		
2.8.5.2 (1.0144 resp. S testing alumin <i>Manual of Tes</i> substance bein	For it 44-3), ium, no its and g tested	the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR, ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for on-clad, types 7075–T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the <i>Criteria</i> , Part III, Section 37. Where an initial test on either steel or aluminium indicates the is corrosive the follow up test on the other metal is not required.		

2.8.5.3 Liquids, and solids which may become liquid during transport, which are judged not to be corrosive to skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.3.1 and 2.8.3.2 above.

2.8.5.4 Packing Group III is assigned in accordance with Table 2.8.3 below

### **Table 2.8.3**

Packing Group	Effect
III	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