COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the
Transport of Dangerous Goods

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ISSUES RELATING TO THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Suggested text for implementation of the GHS criteria in Class 8 of the UN Model Regulations on the Transport of Dangerous Goods for consideration by the experts on the transport of dangerous goods.

Addendum to ST/SG/AC.10/C.3/2009/15 (Netherlands)

Transmitted by the expert from the Netherlands

1. Reference is made to document ST/SG/AC.10/C.3/2009/15.

2. Annex 1 to this informal document contains the comments made by members of a correspondence group on the proposals contained in informal document UN/SCETDG/33/INF.17, as well as the comments and responses by the expert from the Netherlands.

3. Annex 2 is a track change version of information document UN/SCETDG/33/INF.17 showing the changes proposed following these consultations.

Annex 1

Comments given and our responses

		paragraph	Comment	Response
1	Germany	General Remarks	The proposal by the Netherlands for the implementation of GHS criteria in Class 8 of the UN Recommendations on the Transports of Dangerous Goods is highly appreciated. As identified in document ST/SG/AC.10/C.3/2008/48, major differences between both systems remain, which concern in particular the type of information specified for use in classification decisions and the procedures for the classification of mixtures. However, the same classification criteria are already used for the assignment of substances to Packing Groups I-III in Class 8, UN TDG, and the subcategories A-C in the GHS category 'skin corrosive', respectively. In view of the reluctance of some delegations to accept the far-reaching changes to the TDG text as proposed by the Netherlands in document UN/SCETDG/33/INF.17, we have prepared a modified proposal for changes to the TDG text, which attempts to retain the original text to a greater extent, and which we present to the Netherlands for kind consideration.	The proposal as prepared by Germany is closer to the UN TDG text. For reasons of transparency in the process of classification and assignment of the packaging group we prefer to stick to a 2-step procedure. By presenting the classification criteria separate from the assignment of the packaging group, the text can easily be adapted due to future changes in the GHS text/criteria.
2	Sweden	General comment	We also believe it would be advantageous to include the proposed text in the UN Recommendations, instead of only inserting a reference. In GHS there are parts dealing with skin irritation which should not be considered for transport, and if we only insert a reference to GHS from the UN Recommendations, it seems we would have to include a lot of text in the UN Rec. explaining which parts apply and which parts that do not apply for transport. Therefore, we think it is more helpful to insert a complete text in the UN Rec., adjusted to the transport regulations. In addition, it is beneficial to have the complete set of requirements in one book.	The present proposal is to include the GHS criteria.

		paragraph	Comment	Response
3	SGCI Chemie Pharma Schweiz	General comment	Die starke Bewertung des pH-Wertes mit der Anmerkung, dass bei Über- bzw. Unterschreitung der Grenzwerte eine Einstufung in die PG I oder wenn dies nicht erfolgen soll, ein in vitro-Test erforderlich ist, führt dazu dazu dass der Prüfaufwand, besonders bei Zubereitungen, exorbitant steigt. Hier sollte sich wenigstens bei Zubereitungen die worst-case Einstufung an der Bewertung der kritischsten Einzelkomponente ausrichten. Selbst bei diesem Scenario würde sich der Prüfaufwand sehr stark erhöhen.	This comment is related to the content of the GHS criteria. We consider this outside the scope of the alignment of the Regulation with the GHS criteria. SGCI can bring this comment forward in the Sub-Committee of Experts on GHS.
4	SGCI Chemie Pharma Schweiz	General comment	- Die Terminologie im Gefahrgutrecht sollte konsistent gehalten werden. Ähnlich wie bei der Übernahme der Kriterien für wassergefährdende Stoffe weitestgehend gelungen, sollten nicht Begriffe aus dem GHS übernommen werden, welche im Gefahrgutrecht bereits ein Pendant besitzen.	We hope the present proposal is consistent with the UN TDG terminology.
5	SGCI Chemie Pharma Schweiz	General comment	- Direkte Verweise auf das GHS sind zu vermeiden, da das GHS international nicht bindend ist und somit in einzelnen Ländern / Regionen diese Quellen ggf. keinerlei Rechtskraft besitzen oder weitestgehend unbekannt sind. (Beispiel hierzu ist der Abschnitt 2.8.4 in dem auf einen Entscheidungsbaum verwiesen wird, welcher in Begrifflichkeit und Inhalt nur in Teilen anwendbar ist.)	The present proposal is to include the GHS criteria.
6	SGCI Chemie Pharma Schweiz	General comment	- Da die Einführung eines neuen Systems zur Bewertung korrosiver Stoffe und Mischungen auf jeden Fall zu einem hohen Prüfaufwand und umfangreichen Neubewertungen führt, ist sicherzustellen dass diese Regelungen nur nach langer Übergangszeit und unter Prüfung der internationalen Umsetzungsgeschwindigkeit des GHS in Kraft treten. Auf keinen Fall kann eine Harmonisierung vor der Umsetzung des GHS in weiten Teilen der Welt erfolgen. Auch hierzu kann die Einführung der Kriterien für wassergefährdende Stoffe als Beispiel für anderenfalls negative Auswirkungen dienen: Da die Kriterien in den USA bisher weitgehend unbekannt waren und somit der Aufwand einer Umstellung sehr hoch, hat US-DOT beschlossen vorerst die alten Regeln zur	The normal procedures regarding the changes in UN TDG can be applied in this case.

		paragraph	Comment	Response
			Einstufung dieser Stoffe bei zu behalten. Da jedoch UN-Nr. und andere Elemente weltweit harmonisiert sind, führt dies aktuell zu unterschiedlichen Aussagen bei identischer Verwendung einer UN-Nummer. Da im Gegensatz zu einer Anwendung in Anlagen, das Transportrecht die Verbringung der Ware auch zwischen vollkommen unterschiedlichen Rechtszuständigkeiten regelt, wären weitere Abweichungen auch im Bereich der ätzenden Stoffe fatal und würden das Schutzziel eher konterkarieren.	
7	Canada	2.8.1	Editorial (3x)	Accepted
8	Canada	2.8.2.2	Editorial (3x)	Accepted
9	Germany	2.8.2.2.	Text proposals: 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 or synthetic skin in accordance with the criteria in 2.8.2.4, which correspond to the GHS criteria for the classification for skin corrosion. Liquids, and solids which may become liquid during transport, which are judged not to cause full thickness destruction of human or synthetic 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), which correspond to the GHS classification ‘corrosive to metal’.	Text proposals are accepted. The references to paragraphs are adapted to the paragraph numbering in the present proposal.
10	Canada	2.8.2.3	Editorial (1x)	Accepted
11	Canada	2.8.2.4	Editorial (3x)	Accepted
12	Germany	2.8.2.4	Proposal to include ‘or on surrogate information as described in 2.8.3.2’ as a source of information on skin corrosion.	Accepted
13	Germany	2.8.2.5	Proposal to re-install the UN TDG text, resulting in a direct conclusion regarding packaging groups from the test results.	We prefer to conclude the packaging group from the GHS corrosion conclusion.

		paragraph	Comment	Response
				GE proposal not included in present proposal.
14	DGAC	2.8.3	(summarized) The text in 2.8.3 states, with respect to pH, that “there is merit in considering the totality of existing information and making an overall weight of evidence determination” but it’s unclear whether this could overturn a pH measurement. The text is simply too vague and in our view should be revised to indicate that this parameter may be used to help determine whether a substance is corrosive but is not a conclusive indicator.	We have sympathy for the comment regarding the need for explicit inclusion of the possibility to overturn the pH measurement by additional testing. The text describing the criteria for mixtures included in GHS 3.2.3.1.2 does explicitly mention the possibility of further testing to confirm the corrosive properties of a mixture. The text in 2.8.3 is adapted; The possibility to overturn the pH measurement by additional testing (preferably by the use of an appropriate validated *in vitro* test) is included. (see also changes in note (c) to Figure 2.8.1. Furthermore: the results of in *vitro* test OECD 435 allow determination of PG.
15	DGAC	2.8.3	(summarized) pH-value cannot be used to determine subcategory of classification category corrosive, and the assignment of packaging group.	The text in 2.8.3 is adapted; The possibility to overturn the pH measurement by additional testing (preferably by the use of an appropriate validated *in vitro* test) is included.
16	SGCI Chemie Pharma Schweiz	2.8.3	(summarized) support for DGAC comments on paragraph 2.8.3. A number of companies use the pH only.	For a reaction on the DGAC comments, see above. The text allows to use the pH value to determine the corrosivity, and the text in 2.8.3 is adapted to include explicitly the possibility to overturn the pH measurement by additional testing (preferably by the use of an appropriate validated *in vitro* test) is included.

		paragraph	Comment	Response
17	Sweden	2.8.3.1	We believe “hazard classes” should be changed to “hazard categories” because we already use “hazard classes” in the transport regulations when classes 1 to 9 are discussed.	In the GHS text ‘hazard categories’ is used, comment accepted.
18	Canada	2.8.3.2	Editorial (4x)	Accepted
19	Canada	2.8.3.3	Editorial (7x)	Accepted
20	Netherlands	2.8.3.3	Last sentence deleted: ‘The following table indicates all relevant GHS steps for corrosivity’ This sentence did not add to the clarity of the text.	
21	Netherlands	Figure 2.8.1	In the heading the word ‘potential’ is added. This brings the heading in line with the GHS text	
22	Netherlands	Figure 2.8.1	Note (c)	The text in note (c) to Figure 2.8.1 is expanded; The possibility to overturn the pH measurement by additional testing (preferably by the use of an appropriate validated *in vitro* test) is included.
23	Sweden	Figure 2.8.1	In paragraph (g) – should be amended to (f)	Accepted
24	Sweden	Figure 2.8.1	The last sentence in (f) applies to skin irritation and should be deleted.	The last sentence of (f) is only applicable in situations were ‘Human patch testing’ is performed to identify the irritating properties of a substance. The OECD test guidelines are not related to the anecdotal evidence referred to in Step 1a in Figure 2.8.1. Accepted
25	Netherlands	Figure 2.8.1	Editorial	
26	Canada	2.8.3.4	Editorial (4x)	Accepted
27	Netherlands	2.8.3.4.2	For completeness the reference to OECD test guideline 404 (*in vivo* skin irritation/corrosion) is added.	
28	Netherlands	2.8.4.1.2	‘and irritation’ deleted. ‘preparation’ replaced with ‘mixture’, to bring the paragraph in line with the GHS text.	
29	Canada	2.8.4.2.1	Editorial (2x)	Accepted

		paragraph	Comment	Response
30	Canada	2.8.4.2.2	Editorial (1x) and Reference to paragraph 2.8.5.3 should be changed to paragraph 2.8.4.3.	Accepted
31	Sweden	2.8.4.2.2	Section 2.8.5.3 does not exist and should probably be 2.8.4.3.	Accepted
32	Canada	2.8.4.2.3.	Editorial (1x)	Accepted
33	Germany	2.8.4.2.3	Is this clause relevant for the transport sector?	This clause might be relevant for consigners.
34	Canada	2.8.4.2.4	Editorial (1x)	Accepted
35	Canada	2.8.4.2.5	Editorial (4x)	Accepted
36	Canada	2.8.4.2.6	Editorial (2x)	Accepted
37	Canada	2.8.4.3	Editorial in title of the paragraph (1x)	Accepted, and additionally 'component' is replaced with 'ingredient'(2x)
38	Sweden	2.8.4.3.	.8.4.3: Should be amended to 2.8.4.3.	Accepted
39	Canada	2.8.4.3.2	Replace 'component' with 'ingredient'	In the GHS text 'ingredient' is used, comment accepted.
40	Netherlands	Table 2.8.3 & 2.8.4	Tables moved to a different position in the chapter for editorial reasons.	
41	Canada	2.8.4.3.4	Editorial (2x)	Accepted
42	Netherlands	2.8.4.3.4	Editorial (Corrosive replaced by Skin corrosive)	
43	Canada	2.8.4.3.5	Editorial (1x)	Accepted
44	Germany	2.8.4.3.5	Replace 'In those cases the tiered weight of evidence strategy should be applied' with 'In those cases *in vitro* methods or alternative approaches should be considered'	This proposal is not included; we preferred to stay in line with the GSH text.
45	Canada	2.8.4.3.6	Editorial (3x)	Accepted
46	Sweden	Note to Table 2.8.3	In the Note to table 2.8.3, the first sentence after the deleted sentence should begin "The sum…", to make the sentence clear.	Accepted
47	Sweden	Note to Table 2.8.3	Furthermore, since the table is different from the one in GHS, the second sentence, starting: "In case the sum…", is not necessary because now it is only repeating what is already stated in the table. (In GHS, the table includes skin irritation and in that case the explanation in the second sentence is needed).	The Note to Table 2.8.3 explains the content in the table. We prefer to keep the 2nd and 3rd sentence in the Note as it explains the summation rule for corrosive subcategories.

		paragraph	Comment	Response
48	Canada	Note to table 2.8.3	Editorial (1x)	Accepted
49	Canada	2.8.5	Editorial (2x)	Accepted
50	Canada	2.8.6	Editorial (2x)	Accepted
51	Canada	Table 2.8.5	Add to the Criteria applicable for category 1: ‘when tested on both materials (see note below)’	This aligns the proposed text with GHS table 2.16.1, Accepted
52	Canada	2.8.6.1	Editorial in title of paragraph	Accepted
53	Canada	2.8.6.1(a)	Editorial	Accepted

Annex 2

Changes to UN/SCETDG/33/INF.17, presented as track changes

Chapter 2.8

CLASS 8 – Corrosive substances

2.8.1.1 Definitions

Class 8 substances (corrosive substances) are substances which, by chemical action, will cause severe damage when in contact with living tissue, or, in the case of leakage, will materially damage, or even destroy other goods or means of transport.

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.

A substance or a mixture that is *corrosive to metal* is a substance or a mixture which, by chemical action, will materially damage, or even destroy, metals.

2.8.1.2 Assignment of packing groups

2.8.2.1 Substances and preparations 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 and preparations;

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

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

2.8.2.2 Allocation of substances listed in the Dangerous Goods List in Chapter 3.2 to the packing groups in Class 8 has been made on the basis of experience taking into account such additional factors as inhalation risk (see 2.8.2.3) 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 ~~their GHS classification. The GHS classification for skin corrosion reflects~~ the length of time of contact necessary to produce full thickness destruction of human or synthetic skin in accordance with the ~~GHS~~ criteria. in 2.8.3.4, which correspond to the GHS criteria for the classification for skin corrosion. Liquids, and solids, which may become liquid during transport~~,~~ and 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~~. This metal corrosion potential is reflected in~~ in accordance with the criteria in 2.8.6, which correspond to the GHS classification ‘corrosive to metal’.

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

2.8.2.4 In assigning the packing group to a substance in accordance with 2.8.2.2, 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 Guideline 404[1] or 435[2] or on surrogate information as described in 2.8.3.2. A substance, which is determined not to be corrosive in accordance with OECD Test Guideline 430[3] or OECD Test Guideline 431[4], may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

2.8.2.5 Packing groups are assigned to corrosive substances and mixtures in accordance with the following criteria:

Table 2.8.1 Assignment of packing group to substances and mixtures based on Skin corrosive subcategory or metal corrosion category

	Classification of substance or mixture	
Packing group I	Skin corrosive subcategory 1A	
Packing group II	Skin corrosive subcategory 1B	
Packing group III	Skin corrosive subcategory 1C	Corrosive to metal Category 1

The classification criteria for skin corrosion are included in 2.8.3. (substances) and 2.8.4 (mixtures).

The classification criteria for corrosive to metal are included in 2.8.6.

2.8.2 Classification criteria for substances as skin corrosive

2.8.3.1 The GHS harmonized system includes guidance on the use of data elements that are evaluated before animal testing for skin corrosion is undertaken. It also includes hazard ~~classes~~ categories for corrosion.

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[1] *OECD Guideline for the testing of chemicals No. 404 "Acute dermal irritation/Corrosion" 1992.*
[2] *OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006.*
[3] *OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.*
[4] *OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2004.*

2.8.3.2 Several factors should be considered in determining the corrosion potential of chemicals before testing is undertaken. Existing human experience and data, including from single or repeated exposure, and animal observations and data should be the first line of analysis, as they give information directly relevant to effects on the skin. In some cases enough information may be available from structurally related compounds to make classification decisions. Likewise, pH extremes like < 2 and > 11.5 may indicate skin effects, especially when buffering capacity is known, although the correlation is not perfect. Generally, such agents are expected to produce significant effects on the skin. If consideration of alkali/acid reserve suggests the substance may not be corrosive despite the low or high pH value, then further testing shall be carried out to confirm this, preferably by use of an appropriate validated *in vitro* method. It also stands to reason that if a chemical 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, additional testing would not be needed, provided that the dilutions used and species tested are equivalent. *In vitro* alternatives that have been validated and accepted may also be used to help make classification decisions.

All the above information that is available on a chemical should be used in determining the need for *in vivo* skin irritation testing. Although information might be gained from the evaluation of single parameters within a tier (see 2.8.3.3), e.g. caustic alkalis with extreme pH should be considered as skin corrosives, there is merit in considering the totality of existing information and making an overall weight of evidence determination. This is especially true when there is information available on some but not all parameters. Generally, primary emphasis should be placed upon existing human experience and data, followed by animal experience and testing data, followed by other sources of information, but case-by-case determinations are necessary.

2.8.3.3 A *tiered approach* to the evaluation of initial information should be considered, where applicable (Figure 2.8.1), recognizing ~~recognising~~ that all elements may not be relevant in certain cases.

Figure 2.8.1: Tiered testing and evaluation of skin corrosion potential

Step	Parameter		Finding		Conclusion
1a	Existing human or animal experience [f]	→	Corrosive	→	Classify as corrosive [a]
	Not corrosive or no data				
1b	Existing human or animal experience	→	Not corrosive	→	No further testing, not classified
	No data				

2~~a~~	Structure-activity relationships or structure-property relationships [(b)]	→	Corrosive	→	Classify as corrosive [(a)]
	Not corrosive or no data				
3	pH with buffering [(c)]	→	pH ≤ 2 or ≥11.5	→	Classify as corrosive [(a)]
	Not pH extreme or no data				
4	Existing skin data in animals indicate no need for animal testing [(d)]	→	Yes	→	Possibly no further testing may be deemed corrosive
	No indication or no data				
5	Valid and accepted in vitro skin corrosion test [(e)]	→	Positive response	→	Classify as corrosive [(a)]
	Negative response or no data				
6	*In vivo* skin corrosion test (1 animal)	→	Corrosive response	→	Classify as corrosive [(a)]
	Negative response	→	Non-corrosive response	→	No further testing, not classified

(a) Classify in the appropriate harmonized category, as shown in Table 2.8.2 below;

(b) Structure-activity and structure-property relationships are presented separately but would be conducted in parallel;

(c) Measurement of pH alone may be adequate, but assessment of acid or alkali reserve is preferable; methods are needed to assess buffering capacity; If consideration of alkali/acid reserve suggests the substance may not be corrosive despite the low or high pH value, then further testing shall be carried out to confirm this, preferably by use of an appropriate validated in vitro method.

(d) Pre-existing animal data should be carefully reviewed to determine if in vivo skin corrosion/irritation testing is needed. For example, testing may not be needed when a test material has not produced any skin irritation in an acute skin toxicity test at the limit dose, or produces very toxic effects in an acute skin toxicity test. In the latter case, the material would be classified as being very hazardous by the dermal route for acute toxicity; it is moot whether the material is also irritating or corrosive on the skin. It should be kept in mind in evaluating acute skin toxicity information that the reporting of skin 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;

(e) Examples of internationally accepted validated in vitro test methods for skin corrosion are OECD Test Guidelines 430, 431 and 435;

(f) This evidence could be derived from single or repeated exposures. ~~There is no internationally accepted test method for human skin irritation testing, but an OECD guideline has been proposed;~~

2.8.3.4 *Corrosion subcategories*

2.8.3.4.1 A single harmonized corrosion category is provided in Table 2.8.2 using the results of animal testing. A corrosive is a test material that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 tested animals after exposure up to a 4-hour duration. Corrosive reactions are typified by ulcers, bleeding, bloody scabs and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia and scars. Histopathology should be considered to discern questionable lesions.

2.8.3.4.2 Three subcategories are provided within the corrosive category (see Table 2.8.2): subcategory 1A - where responses are noted following up to 3 minutes exposure and up to 1 hour observation; subcategory 1B - where responses are described following exposure between 3 minutes and 1 hour and observations up to 14 days; and subcategory 1C - where responses occur after exposures between 1 hour and 4 hours and observations up to 14 days. The classification within a subcategory can be reached based on the results of *in vitro* (OECD 435) or *in vivo* testing (OECD 404).

Table 2.8.2 Skin corrosive category and subcategories

Category 1: Corrosive	**Corrosive subcategories**	**Corrosive in ≥ 1 of 3 animals**	
		Exposure	**Observation**
Corrosive	1A	≤ 3 minutes	≤ 1 hour
	1B	> 3 minutes -- ≤ 1 hour	≤ 14 days
	1C	> 1 hour -- ≤ 4 hours	≤ 14 days

2.8.4 Classification criteria for mixtures as skin corrosive

2.8.4.1 *Classification of mixtures when data are available for the complete mixture*

2.8.4.1.1 The mixture will be classified using the criteria for substances, and taking into account the testing and evaluation strategies to develop data for these hazard classes.

2.8.4.1.2 Unlike other hazard classes, there are alternative tests available for skin corrosivity of certain types of chemicals that can give an accurate result for classification purposes, as well as being simple and relatively inexpensive to perform. When considering testing of the mixture classifiers are encouraged to use a tiered weight of evidence strategy as included in the criteria for classification of substances for skin corrosion ~~and irritation~~ to help ensure an accurate classification, as well as avoid unnecessary animal testing. A mixture is considered corrosive if it has a pH of 2 or less or a pH of 11.5 or greater. If consideration of alkali/acid reserve suggests

the substance or ~~preparation~~ mixture may not be corrosive despite the low or high pH value, then further testing needs to be carried out to confirm this, preferably by use of an appropriate validated *in vitro* test.

2.8.4.2 ***Classification of mixtures when data are not available for the complete mixture: Bridging principles***

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

2.8.4.2.2 Dilution

If a mixture is diluted with a diluent which has an equivalent or lower corrosivity classification than the least corrosive original ingredient and which is not expected to affect the corrosivity of other ingredients, then the new mixture may be classified as equivalent to the original mixture. Alternatively, the method explained in section 2.8.~~5~~ 4.3 could be applied.

2.8.4.2.3 Batching

The corrosion potential of one production batch of a complex mixture can be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the batch has changed. If the latter occurs, new classification is necessary.

2.8.4.2.4 Concentration of mixtures of the highest corrosion category

If a tested mixture classified in the highest subcategory for corrosion is concentrated, a more concentrated mixture should be classified in the highest corrosion subcategory without additional testing.

2.8.4.2.5 Interpolation within one toxicity category

For three mixtures with identical ingredients, where A and B are in the same corrosion toxicity category and mixture C has the same toxicologically active ingredients with concentrations intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same corrosion category as A and B.

2.8.4.2.6 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 corrosion for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the toxicity of B.

If mixture (i) is already classified based on test data, then mixture (ii) can be classified in the same category.

2.8.4.3 *Classification of mixtures when data are available for all ~~components~~ ingredients or only for some ~~components~~ ingredients of the mixture*

2.8.4.3.1 In order to make use of all 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 of 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g. in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for skin corrosion.

2.8.4.3.2 In general, the approach to classification of mixtures as corrosive to skin when data are available on the ~~components~~ ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive ~~component~~ ingredient contributes to the overall or corrosive properties of the mixture in proportion to its potency and concentration. The mixture is classified as corrosive when the sum of the concentrations of such components exceeds a cut-off value/concentration limit.

2.8.4.3.3 Table 2.8.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be a corrosive to the skin.

Table 2.8.3: Concentration of ingredients of a mixture classified as Skin corrosive, that would trigger classification of the mixture as Skin corrosive.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:		
	Skin corrosive		
	Category 1A (see note below)	**Category 1B**	**Category 1C**
Skin Category 1A	≥5%		
Skin Category 1A + 1B		≥5%	
Skin Category 1A + 1B + 1C			≥5%

***Note to Table 2.8.3**: ~~If the~~ The sum of all ingredients of a mixture classified as Skin Category 1A, 1B or 1C respectively, should each be ≥ 5% in order to classify the mixture as either Skin Category 1A, 1B or 1C. In case the sum of the Skin Category 1A ingredients is <5% but the sum of Skin Category ingredients 1A+1B is ≥5%, the mixture should be classified as Skin Category 1B. Similarly, in case the sum of Skin Category 1A+1B is <5% but the sum of Category 1A+1B+1C is ≥5% the mixture would be classified as Category 1C.*

2.8.4.3.4 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 2.8.4.3.1 and 2.8.4.3.2 might not work given that many of such substances are corrosive at concentrations < 1%. For mixtures containing strong acids or bases the pH should be used as classification criteria (see 2.8.4.1.2) since pH will be a better indicator of corrosion than the concentration limits of Table 2.8.3. A mixture containing corrosive ingredients that cannot be classified based on the additivity approach shown in Table 2.8.3, due to chemical characteristics that make this approach unworkable, should be classified as ~~Corrosive~~ Skin corrosive if it contains ≥ 1% of a corrosive ingredient. Classification of mixtures with ingredients for which the approach in Table 2.8.3 does not apply is ~~summarised~~ summarized in Table 2.8.4 below.

Table 2.8.4: **Concentration of ingredients of a mixture for which 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 ≤ 2	≥ 1%	Category 1
Base with pH ≥11.5	≥ 1%	Category 1
Other corrosive (Category 1) ingredients for which additivity does not apply	≥ 1%	Category 1

2.8.4.3.5 On occasion, reliable data may show that the skin corrosion of an ingredient will not be evident when present at a level above the generic concentration cut-off levels mentioned in Tables 2.8.3 – 2.8.4. In these cases the mixture could be classified according to that data (see also *Classification of Hazardous Substances and Mixtures* – Use of Cut-Off Values/Concentration Limits (UN Globally Harmonized system of Classification and Labelling of Chemicals paragraph 1.3.3.2)). On occasion, when it is expected that the skin corrosion of an ingredient will not be evident when present at a level above the generic concentration cut-off levels mentioned in Tables 2.8.3 and 2.8.4 testing of the mixture may be considered. In those cases the tiered weight of evidence strategy should be applied as described in 2.8.4.1.4 and illustrated in Figure 2.8.1.

2.8.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive at a concentration of < 1% (corrosive), the mixture should be classified accordingly (see also *Classification of Hazardous Substances and Mixtures – The Use of Cut-Off Values/Concentration Limits* (UN Globally Harmonized system of Classification and Labelling of Chemicals paragraph 1.3.2.3.1.2)).

2.8.5 Decision Logic for skin corrosion/irritation

In the UN Globally Harmonized system of Classification and Labelling of Chemicals Chapter 3.2, a decision logic is presented. This decision logic is not part of the harmonized classification system but is provided as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of the decision logic.

2.8.6 Classification criteria for substance and mixtures corrosive to metal

A substance or a mixture, which is corrosive to metals, is classified in a single category for this class, using the testing in part III, sub-section 37 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, according to the following table:

Table 2.8.5 : Criteria for substances and mixtures corrosive to metal

Category	Criteria
1	Corrosion rate on steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55 °C. when tested on both materials (see note below).

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

2.8.6.1 Guidance

The corrosion rate can be measured according to the test method of sub-section 37.4 of the UN Recommendations on the Transport of Dangerous Goods, Manual of tests and Criteria. The specimen to be used for the test should be made of the following materials:

(a) For the purposes of testing steel, steel types S235JR+CR (1.0037 resp.St 37-2), S275J2G3+CR (1.0144 resp.St 44-3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 1020.

(b) For the purposes of testing aluminium: non-clad types 7075-T6 or AZ5GU-T6.

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