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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

Thirty-fifth session
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Item 10 of the provisional agenda

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

Transmitted by the expert from the Netherlands[1]

Introduction

1. The alignment of criteria for corrosivity in the UN Model Regulations on the Transport of Dangerous Goods with the GHS criteria was discussed during the 34th session of the Sub-Committee (ST/SG/AC.10/C.3/68 para 108 – 111). Following the discussions the expert from The Netherlands agreed to lead a correspondence group in the biennium 2009-2010 with the aim to elaborate the alignment of the corrosivity criteria (ST/SG/AC.10/C.3/68 para 120).

2. In this working document the input of the correspondence group is summarized. Furthermore a revised proposal for the alignment of the corrosivity criteria in Chapter 2.8 with the GHS is presented.

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[1] In accordance with the programme of work of the Sub-Committee for 2009-2010 approved by the Committee at its fourth session (refer to ST/SG/AC.10/C.3/68, para. 118(i) and ST/SG/AC.10/36, para. 14).

Correspondence Group

3. The expert from the Netherlands invited the members of the Sub-Committee to present written comments regarding the proposal on the alignment of the UN Model Regulations with GHS as presented in informal document INF.17 submitted at the 33rd session.

4. Constructive comments were received from the experts from Canada, Sweden, Germany and representatives of DGAC and ICCA (SGCI (Chemie Pharma, Schweiz)). The comments and our response by the expert from the Netherlands are presented in Annex 1 of informal document INF.3. The resulting changes to informal document INF.17 submitted at the 33rd session are presented as track changes in Annex 2 to informal document INF.3.

5. In line with the discussions during the 33rd and 34th sessions of the Sub-Committee, the most eye-catching point raised in the written comments was the concern regarding the use of pH values in the classification process. In line with the GHS text for mixtures the possibility to overturn the information of the pH values is included in 2.8.4.1.2 as follows:

> "If consideration of alkali/acid reserve suggests the substance or 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."

Though not explicitly mentioned in the GHS this principle is also valid for substances. To explicitly include this principle in the Regulation the text referred to above is added to the classification of substances in 2.8.3.2 and Figure 2.8.1 note (c).

Proposal

6. For the sake of harmonization of the UN Model Regulations with the GHS, the annex to this document contains the proposal for a revised of Chapter 2.8.

Annex

Chapter 2.8

Class 8 – Corrosive substances

2.8.1 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.

2.8.2 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 the length of time of contact necessary to produce full thickness destruction of human or synthetic skin in accordance with the criteria in 2.8.3.4, 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 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[2] or 435[3] 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[4] or OECD Test Guideline 431[56], 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.

2.8.3 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 categories for corrosion.

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[2] OECD Guideline for the testing of chemicals No. 404 "Acute dermal irritation/Corrosion" 1992.
[3] OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006.
[4] OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.
[5] 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 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 ↓				

2a	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.

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 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 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 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 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 2.8.4.3 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 ingredients or only for some 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 ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive 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*: 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 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 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.