UN/SCETDG/41/INF.27
UN/SCEGHS/23/INF.11

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

Forty-first session

Geneva, 25 June – 4 July 2012

Item 10 (a) of the provisional agenda

Issues relating to GHS and labelling of chemicals: Corrosivity criteria

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Twenty-third session

Geneva, 4 – 6 July 2012

Item 4 © of the provisional agenda

Implementation of GHS: Cooperation with other bodies or international organisations

Harmonisation of the skin corrosion classification criteria in the UN Model Regulations with those in GHS

Transmitted by the European Chemical Industry Council (CEFIC)

Summary

Based on the outcome of the discussions at the last meeting of the Joint TDG-GHS group on corrosivity criteria this document proposes to harmonise chapter 2.8 of the UN Model Regulations with GHS taking into account the specific impact on transport conditions. This is achieved firstly by adding GHS text which is not already in the UN Model Regulations but which has been slightly amended regarding specific TDG terms and numbering, and secondly by introducing, based upon a risk approach, provisions for the assignment of Packing Groups to mixtures and solutions for which the additivity approach does not apply

Background

1. The Joint TDG-GHS group on corrosivity criteria agreed at its last meeting during the 40th session of the UN Subcommittee of the Transport on Dangerous Goods (see UN/SCETDG/40/INF.51), that its objective was:

- One classification for a substance or mixture for both transport and supply/use and based on hazard,
- The assignment of packing groups for transport based on hazard and risk.

Introduction

2. The outcome of the discussion at the last meeting of the joint TDG-GHS group was as follows:

- The criteria for the classification based on test data are already harmonised, including the available OECD test guidelines.
- The use of alternative methods to testing (e.g. the use of bridging principles or calculation methods) for classifying mixtures, are allowed under current provisions of the UN Model Regulations. If this option should not be clear from the current provisions of the UN Model Regulations, an amendment to the text in Chapter 2.8 might be needed.

3. Based on these conclusions CEFIC sees the need to integrate the GHS skin corrosion criteria for mixtures into the UN Model Regulations, in order to achieve harmonized classification criteria. Therefore CEFIC proposes to incorporate the GHS skin corrosion criteria for mixtures into Chapter 2.8 of the UN Model Regulations, taking account of the risk based assignment of transport conditions. As the non-additive GHS criteria for mixtures are based on the concept of expert judgement and weight of evidence (GHS 1.3.2.4.8 and 1.3.2.4.9), this concept should also be entered into the Model Regulations, either directly in chapter 2.8, but as the concept is valid to all health and environmental hazards, CEFIC suggests incorporation into chapter 2.0 (see separate UN/SCETDG/41/INF.28).

Proposal

4. CEFIC proposes to revise Chapter 2.8 as shown in the left column of the table in Annex I whereby new text has been underlined. In principle the new text is adopted from the corresponding GHS text but, where necessary, adapted concerning numbering, terms (e.g. packing groups instead of categories) and scope (e.g. irritation criteria are not adopted). Text that differs from GHS has been struck-through. For comparison purposes the corresponding text in GHS (based on the current proposal of the informal correspondence group on the editorial revision of Chapters 3.2 and 3.3) has been reproduced in the right column of the table in Annex I.

Justification

5. Annex II lists examples which emphasize the importance of the assignment of Packing Group II in table 2.8.6.8 and in paragraph 2.8.4.4. During the discussion in the TDG/GHS correspondence group at the June 2011 meeting there was consensus that in case the non-additivity approach is applicable (see 2.8.4.3 and 2.8.6.4) the assignment of Packing Group II should be appropriate rather than Packing Group I. A differentiation into all 3 packing groups is possible following the rules in 2.8.4.4. Prerequisite was that Industry can provide examples to confirm the validity of this approach: these are offered in Annex II.

6. Annex III lists the n.o.s. entries of Class 8 substances without sub risks with the corresponding packing and tank instructions and hereby provides an impression of the impact of imposing stricter packing groups. It is important to note that the transport conditions based on the current regulatory provisions have proved to guarantee safe transport for decades.

7. Without adequate safety-relevant justification, significant changes in the assignment of the packing group will lead to severe operational difficulties, as the use of certain types of packagings and tanks will be prohibited. Many shippers and consignees will therefore have to reconstruct their facilities in order to be able to continue filling and discharging operations. Additionally, the assignment of PG I might also exclude Class 8 substances from shipments by air, and as limited or excepted quantities.

8. IBCs are generally not approved for the transport of PG I liquid products whereas the transport of PG I solid products is only permitted with additional logistic restrictions and making use of a limited selection of IBC construction types. As a result the established filling and discharge procedures will have to be adapted to handle alternative packagings like drums. However the capacity of these packagings is generally limited to a filling volume of about 220 litres so that the number of handlings, shipments and associated risks will significantly increase, on top of the additional costs.

9. On the other hand the extremely low number of incidents reported on IBC shipments of dangerous goods, indicate that IBCs are an appropriate means to safely handle and transport dangerous goods, including Class 8 products.

10. Tanks required for substances of Packing Group I have to comply with high minimum test pressures and are therefore heavier than tanks required for Packing Group II substances. As a consequence the number of bulk transport operations, necessary to carry the same amount of product, will increase in relation to what is necessary for substances of packing groups II or III. Additionally, for substances of Packing Group I only tanks without bottom valves, i.e. only top loading and unloading operations are permitted so that loading and unloading facilities designed for bottom valves will have to be adapted. It should also be noted that the availability of tank equipment for PG I substances could become critical with respect to creating supply bottlenecks and delivery failures.

11. In addition to the chemical industry, also the ore processing industry and incineration plants will be affected via numerous side-products which are assigned to Class 8 and which are transported in large quantities for further processing.

12. Overall, the assignment of stricter packing groups will result into significant downstream consequences, without corresponding safety benefits, and will even lead to higher operational risks in the transport of packed goods of Class 8.

Annex I

Comparison between the proposed text of Chapter 2.8 in the UN Model Regulations and the text in Chapter 3.2 of GHS

UN Model Regulations	**GHS**
CHAPTER 2.8	**CHAPTER 3.2**
CLASS 8 - CORROSIVE SUBSTANCES	**SKIN CORROSION/IRRITATION**
2.8.1 Definition	**3.2.1 Definitions and general considerations**
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 the means of transport.	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 hoursF[1]F 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 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[1].
	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 case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (see 1.3.2.4.9). This means that 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.
2.8.2 Assignment of packing groups	**3.2.2 Classification criteria for substances** **3.2.2.1 Substance classification based on standard animal test data** **3.2.2.1.1 *Skin Corrosion***

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

<table>
<tr><td>UN Model Regulations</td><td>GHS</td></tr>
<tr><td>CHAPTER 2.8</td><td>CHAPTER 3.2</td></tr>
<tr><td>CLASS 8 - CORROSIVE SUBSTANCES</td><td>SKIN CORROSION/IRRITATION</td></tr>
<tr><td>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.</td><td>3.2.2.1.1.1 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. A corrosive substance is a test material that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 tested animal 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.

3.2.2.1.1.2 For those authorities wanting more than one designation for corrosivity, up to three sub-categories are provided within the corrosive 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 between 3 minutes and 1 hour and observations up to 14 days; and sub-category 1C, where corrosive responses occur after exposures between 1 hour and 4 hours and observations up to 14 days.

Table 3.2.1: Skin corrosion category and sub-categories [a]
<table>
<tr><td>1BCategory 1: Corrosive</td><td>Corrosive sub-categories</td><td colspan="2">2BCorrosive in ≥ 1 animal</td></tr>
<tr><td></td><td></td><td>Exposure</td><td>Observation</td></tr>
<tr><td rowspan="3">corrosive</td><td>1A</td><td>≤ 3 min</td><td>≤ 1 h</td></tr>
<tr><td>1B</td><td>> 3 min ≤ 1 h</td><td>≤ 14 days</td></tr>
<tr><td>1C</td><td>> 1 h ≤ 4 h</td><td>≤ 14 da s</td></tr>
</table></td></tr>
<tr><td>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 skin in accordance with the criteria in 2.8.2.4. Liquids, and solids which may become liquid during transport, which are judged not to cause full thickness destruction of human skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the</td><td></td></tr>
</table>

UN Model Regulations	**GHS**
CHAPTER 2.8	**CHAPTER 3.2**
CLASS 8 - CORROSIVE SUBSTANCES	**SKIN CORROSION/IRRITATION**
criteria in 2.8.2.5 (c) (ii).	
2.8.2.3 A substance or preparation meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC50) 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 Test Guideline 404**1** 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.	
2.8.2.5 Packing groups are assigned to corrosive substances in accordance with the following criteria: (a) *Packing group I* is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period up to 60 minutes starting after the exposure time of three minutes or less; (b) *Packing group II* is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than three minutes but not more than 60 minutes; (c) *Packing group III* is assigned to substances that: (i) cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or (ii) are judged not to cause full thickness destruction of intact skin tissue but which exhibit a corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials. For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR (1.0144 resp. St 44-3), ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for testing aluminium, non-clad, types 7075–T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the *Manual of Tests and Criteria*, Part III, Section 37. ***NOTE:*** *Where an initial test on either steel or aluminium indicates the substance* *being tested is corrosive the follow up test on the other metal is not required.*	

UN Model Regulations	GHS
CHAPTER 2.8	CHAPTER 3.2
CLASS 8 - CORROSIVE SUBSTANCES	SKIN CORROSION/IRRITATION

Table 2.8.2.5: Table summarizing the criteria in 2.8.2.5

Packing Group	***Exposure Time***	***Observation Period***	***Effect***
I	≤ 3 min	≤ 60 min	Full thickness destruction of intact skin
II	> 3 min ≤ 1 h	≤ 14 d	Full thickness destruction of intact skin
III	> 1 h ≤ 4 h	≤ 14 d	Full thickness destruction of intact skin
III	-	-	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 ºC when tested on both materials

Not applicable

3.2.2.1.2 *Skin Irritation*

3.2.2.1.2.1 A single *irritant category (Category 2)* is provided that:

(a) recognizes that some test materials may lead to effects which persist throughout the length of the test; and

(b) acknowledges that animal responses in a test may be quite variable.

An additional *mild irritant category (Category 3)* is available for those authorities that want to have more than one skin irritant category.

3.2.2.1.2.2 Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a material should be considered to be an irritant.

3.2.2.1.2.3 Animal irritant responses within a test can be

UN Model Regulations	GHS
CHAPTER 2.8	CHAPTER 3.2
CLASS 8 - CORROSIVE SUBSTANCES	SKIN CORROSION/IRRITATION

quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a test material might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfil this criterion. However, it should be ascertained that the responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.

3.2.2.1.2.4 A single irritant category (Category 2) is presented in the table using the results of animal testing. Authorities (e.g. for pesticides) also have available a less severe mild irritant category (Category 3). Several criteria distinguish the two categories (Table 3.2.2). They mainly differ in the severity of skin reactions. The major criterion for the irritant category is that at least 2 tested animals have a mean score of $\geq 2.3 \leq 4.0$. For the mild irritant category, the mean score cut-off values are $\geq 1.5 < 2.3$ for at least 2 tested animals. Test materials in the irritant category would be excluded from being placed in the mild irritant category.

Table 3.2.2 Skin irritation categories [a, b]

Categories	3BCriteria
Irritant (Category 2) (applies to all authorities)	(1) Mean score of $\geq 2.3 \leq 4.0$ for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or (2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or (3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the

UN Model Regulations	GHS
CHAPTER 2.8	CHAPTER 3.2
CLASS 8 - CORROSIVE SUBSTANCES	SKIN CORROSION/IRRITATION
	criteria above. **Mild irritant (Category 3)** (applies to only some authorities): Mean score of ≥ 1.5 < 2.3 for erythema/eschar or for oedema from gradings in at least 2 of 3 tested animals from grades at 24, 48 and 72 hours or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions (when not included in the irritant category above).
2.8.3 Substance classification in a tiered approach 2.8.3.1 Existing human and animal data including information from single or repeated exposure should be the first line of analysis, as they give information directly relevant to effects on the skin. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/~~irritation~~ in acute toxicity studies and are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. *In vitro* alternatives that have been validated and accepted should be used to make classification decisions. Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (for packing group assignment see 2.8.4.4) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of alkali/acid 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. In some cases enough information may be available from structurally related substances to make classification decisions. ~~XXXX A *tiered approach* to the evaluation of initial information should be considered, where applicable (Figure XXX), recognizing that not all elements may be relevant.~~ 2.8.3.2 The proposed 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	**3.2.2.2 Substance classification in a tiered approach** 3.2.2.2.1 Existing human and animal data including information from single or repeated exposure should be the first line of analysis, as they give information directly relevant to effects on the skin. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. *In vitro* alternatives that have been validated and accepted should be used to make classification decisions. Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of alkali/acid 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. In some cases enough information may be available from structurally related substances to make classification decisions. 3.2.2.2.2 A *tiered approach* to the evaluation of initial information should be considered, where applicable (Figure 3.2.1), recognizing that not all elements may be relevant. 3.2.2.2.3 The proposed 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).

UN Model Regulations	GHS
CHAPTER 2.8	**CHAPTER 3.2**
CLASS 8 - CORROSIVE SUBSTANCES	**SKIN CORROSION/IRRITATION**
single parameters within a tier ~~(see XXXX)~~, 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.	Although information might be gained from the evaluation of single parameters within a tier (see 3.2.2.2.2), 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.
2.8.4 Classification criteria for mixtures	**3.2.3 Classification criteria for mixtures**
2.8.4.1 *Classification of mixtures when data are available for the complete mixture*	**3.2.3.1 *Classification of mixtures when data are available for the complete mixture***
2.8.4.2 The mixture will be classified using the criteria for substances, and taking into account the tiered approach to evaluate data for this hazard class.	3.2.3.1.1 The mixture will be classified using the criteria for substances, and taking into account the tiered approach to evaluate data for this hazard class.
2.8.4.3 Unlike other hazard classes, there are alternative tests available for skin corrosivity 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. In the absence of any other information, a mixture is considered corrosive [for PG assignment see 2.8.4.4] if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the mixture may not be corrosive despite the low or high pH value, this needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.	3.2.3.1.2 Unlike other hazard classes, there are alternative tests available for skin corrosivity 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. In the absence of any other information, a mixture is considered corrosive (Skin Category 1) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the mixture may not be corrosive despite the low or high pH value, this needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.
NEW TEXT (without corresponding text in GHS) 2.8.4.4 For the assignment of the packing group, the following should apply: - If classified to be corrosive according to the provisions above, the basic assignment should be packing group II. - Packing group I has only to be assigned if other data or other information is available that lead clearly to a classification in a stricter packing group. - If the mixture consists only of components assigned to packing group III and other non-corrosive components or if additional data (e.g. validated in vitro test data) is available, packing group III may be assigned.	
See part 2: general application of bridging principles	**3.2.3.2 *Classification of mixtures when data are not available for the complete mixture: bridging principles***
	3.2.3.2.2 *Dilution*
	3.2.3.2.3 *Batching*
	3.2.3.2.4 *Concentration of mixtures of the highest corrosion/ irritation category*
	3.2.3.2.5 *Interpolation within one toxicity category*

UN Model Regulations	GHS
CHAPTER 2.8	**CHAPTER 3.2**
CLASS 8 - CORROSIVE SUBSTANCES	**SKIN CORROSION/IRRITATION**
	3.2.3.2.6 *Substantially similar mixtures*
2.8.5 *Aerosols* An aerosol form of a mixture may be classified in the same hazard category as the tested non-aerosolized form of mixture provided that the added propellant does not affect the irritation or corrosive properties of the mixture upon spraying.	3.2.3.2.7 *Aerosols* An aerosol form of a mixture may be classified in the same hazard category as the tested non-aerosolized form of mixture provided that the added propellant does not affect the irritation or corrosive properties of the mixture upon spraying.
2.8.6 *Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture*	**3.2.3.3 *Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture***
2.8.6.1 In order to make use of all available data for purposes of classifying the skin corrosion~~/irritation~~ hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach: The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1% (w/w for solids, liquids, dusts, mists and vapors 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.~~	3.2.3.3.1 In order to make use of all available data for purposes of classifying the skin corrosion/irritation hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach: The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1% (w/w for solids, liquids, dusts, mists and vapors 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.
2.8.6.2 In general, the approach to classification of mixtures as ~~irritant or~~ 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 ~~or irritant~~ ingredient contributes to the overall ~~irritant or~~ corrosive 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 when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.~~	3.2.3.3.2 In general, the approach to classification of mixtures as irritant or 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 or irritant ingredient contributes to the overall irritant or corrosive 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 when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.
2.8.6.3 Table 2.8.6.7 below provides the cut-off value/concentration limit~~s~~ to be used to determine if the mixture is considered to be ~~an irritant or a~~ corrosive to the skin.	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 an irritant or a corrosive to the skin.
2.8.6.4 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 2.8.6.1 and 2.8.6.2 might not work given that many of 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 2.8.4.3) since pH will be a better indicator of corrosion than	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 of 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

<table>
<tr><td>UN Model Regulations</td><td>GHS</td></tr>
<tr><td>CHAPTER 2.8</td><td>CHAPTER 3.2</td></tr>
<tr><td>CLASS 8 - CORROSIVE SUBSTANCES</td><td>SKIN CORROSION/IRRITATION</td></tr>
<tr><td>the concentration limits of Table 2.8.6.7. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table 2.8.6.7, due to chemical characteristics that make this approach unworkable, should be classified as packing group II if it contains ≥ 1% of a corrosive ingredient ~~and as skin Category 2/3 when it contains ≥ 3% of an irritant ingredient.~~ Classification of mixtures with ingredients for which the approach in Table 2.8.6.7 does not apply is summarized in Table 2.8.6.8 below.</td><td>corrosion than the concentration limits of 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 Category 1 if it contains ≥ 1% of a corrosive ingredient and as skin Category 2/3 when it contains ≥ 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.</td></tr>
<tr><td>2.8.6.5 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 cut-off values mentioned in Tables2.8.6.7 and 2.8.6.8. 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 2.8.6.7 and 2.8.6.8, 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 ~~and illustrated in Figure 3.2.1.~~</td><td>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 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 strategy should be applied as described in 3.2.3 and illustrated in Figure 3.2.1.</td></tr>
<tr><td>2.8.6.6 If there are data showing that (an) ingredient(s) may be corrosive ~~or irritant~~ 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)).~~</td><td>3.2.3.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant 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)).</td></tr>
<tr><td>Table 2.8.6.7: Concentration of ingredients of a mixture classified as skin corrosive ~~Category 1, 2 or 3~~ that would trigger classification of the mixture as hazardous to skin ~~(Category 1, 2 or 3)~~
<table>
<tr><td rowspan="2">Sum of ingredients classified as:</td><td colspan="3">Concentration triggering classification of a mixture as:</td></tr>
<tr><td>Skin corrosive</td><td colspan="2">~~Skin irritant~~</td></tr>
<tr><td></td><td>Packing group (see note below)</td><td>~~Category 2~~</td><td>~~Category 3~~</td></tr>
<tr><td>Packing group I, II or III</td><td>≥ 5%</td><td>~~≥ 1% but < 5%~~</td><td></td></tr>
<tr><td>~~Skin Category 2~~</td><td></td><td>~~≥ 10%~~</td><td>~~≥ 1% but < 10%~~</td></tr>
<tr><td>~~Skin~~</td><td></td><td></td><td>~~≥ 10%~~</td></tr>
</table></td><td>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)
<table>
<tr><td rowspan="2">Sum of ingredients classified as:</td><td colspan="3">Concentration t iggering classification of a mixture as:</td></tr>
<tr><td>Skin corrosive</td><td colspan="2">Skin irritant</td></tr>
<tr><td></td><td>Category 1 (see note below)</td><td>Category 2</td><td>Category 3</td></tr>
<tr><td>Skin Category 1</td><td>≥ 5%</td><td>≥ 1% but < 5%</td><td></td></tr>
<tr><td>Skin Category 2</td><td></td><td>≥ 10%</td><td>≥ 1% but < 10%</td></tr>
<tr><td>Skin Category 3</td><td></td><td></td><td>≥ 10%</td></tr>
</table></td></tr>
</table>

UN Model Regulations	GHS
CHAPTER 2.8	**CHAPTER 3.2**
CLASS 8 - CORROSIVE SUBSTANCES	**SKIN CORROSION/IRRITATION**

~~Category 3~~			
~~(10 × Skin Category 1) + Skin Category 2~~		~~≥ 10%~~	~~≥ 1% but ≤ 10%~~
~~(10 × Skin Category 1) + Skin Category 2 + Ski Category 3~~			~~≥ 10%~~

(10 × Skin Category 1) + Ski Category 2		≥ 10%	≥ 1% but ≤ 10%
(10 × Skin Category 1) + Skin Category 2 + Skin Category 3			≥ 10%

NOTE:

~~*In case of use of the sub-categories of skin Category 1 (corrosive) , 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.*~~

NEW TEXT (without corresponding text in GHS, but adopting content of deleted text above)

- *In case the sum of packing group I ingredients is ≥ 5% the mixture should be classified as packing group I.*
- *In case the sum of the ~~skin Category 1A~~ packing group I ingredients is ≤ 5% but the sum of ~~skin Category ingredients 1A+1B~~ packing group I and II is ≥ 5%, the mixture should be classified as ~~skin Category 1B~~ packing group II.*
- *Similarly, in case the sum of ~~skin Category 1A + 1B~~packing group I and II is ≤ 5% but the sum of ~~Category 1A + 1B + 1C~~packing group I + II + III is ≥ 5% the mixture would be classified as ~~Category 1C.~~ packing group III*
- ~~*In case at least one relevant ingredient in a mixture is classified as Cat. 1 without sub-categorisation, the mixture should be classified as Cat.1 without sub-categorisation*~~

NOTE:

In case of use of the sub-categories of skin Category 1 (corrosive) , 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.

In case at least one relevant ingredient in a mixture is classified as Cat. 1 without sub-categorisation, the mixture should be classified as Cat.1 without sub-categorisation.

Table 2.8.6.8: 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%	Packing group II*

Table 3.2.4: 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

UN Model Regulations			GHS		
CHAPTER 2.8			**CHAPTER 3.2**		
CLASS 8 - CORROSIVE SUBSTANCES			**SKIN CORROSION/IRRITATION**		
Base with pH ≥ 11.5	≥ 1%	Packing group II*	Base with pH ≥ 11.5	≥ 1%	Category 1
Other corrosive (Category 1) ingredients	≥ 1%	Packing group II*	Other corrosive (Category 1) ingredient	≥ 1%	Category 1
~~Other irritant (Category 2/3) ingredient, including acids and bases~~	~~≥ 3%~~	~~Category 2~~	Other irritant (Category 2/3) ingredient, including acids and bases	≥ 3%	Category 2
*see 2.8.4.4					

Annex II

Examples of mixtures with extreme pH-values, showing evidence not to be classified in Packing Group I

This annex provides examples for mixtures and solutions having an extreme pH-value which requires classification as corrosive to the skin based on the non-additive approach. By tests (example 1) or by the composition (examples 2, 3 and 4) it can be proved that assignment of Packing Group II provides a sufficient level of safety.

Example 1: Extreme pH-value but tested non-corrosive

The example 1 material is a solution having an extreme pH-value. The test results cited prove that the solution is neither corrosive nor irritant for skin or eye. These facts show that the assignment of Packing Group II according the proposed 2.8.4.4 provides a sufficient level of safety.

The solution is used in dental applications for:

- Cementation of inlays, onlays, crowns, and bridges made from metal or metal-ceramics or veneered with composite
- Cementation of inlays, onlays, crowns, and bridges made from composite or ceramics provided these are suitable for conventional cementing
- Cementation of pins and screws provided these are suitable for conventional cementing
- Cementation of orthodontic bands
- Linings (one part of a 2 component system, to be mixed with cement powder)

Formulation				
Hazardous component	CAS no.	Content	Classification according GHS	Classification acc. 67/548/EEC
Water	7732-18-5	50 - 65	Not hazardous	Not hazardous
Polyacrylic acid	9003-01-4	40 - 50	Aqu. chron. 3, H412	R52/53

pH-value	Measured material:
pH-value: 1	100 % product

Tests
1. 2011 OECD 437 (BCOP-test (Bovine Corneal Opacity and Permeability-test): Conclusion: The product did not induce ocular irritation based on mean opacity and permeability values of test article-treated corneas, resulting in a mean in vitro irritancy score of 0.3 after 10 minutes of treatment. Finally, it is concluded that this test is valid and that product is not severe irritant or corrosive in the Bovine Corneal Opacity and Permeability test under the experimental conditions described in this report.

Tests
2. 1995: The experimental procedure used was based on that recommended under Annex V Part B of Directive 79/831/EEC: Methods for the determination of toxicity. B4. Skin irritation and OECD Guideline for Testing of Chemicals No. 404 "Acute Dermal Irritation/Corrosion. (New Zealand White strain rabbits) Conclusion: A single semi-occlusive application of DURELON liquid to intact rabbit skin for four hours elicited temporary, very slight or well-defined dermal irritation. DURELON liquid does not require labelling with the risk phrase R38 "Irritating to skin" as described in the EEC Directive 83/467/EEC Annex VI, Part II (D).

Information on the acid: Polyacrylic acid (CAS 9003-01-4) is not listed in Annex VI of the CLP-regulation. According to the C&L inventory the following different classifications have been notified (only regarding corrosion):

1. Not hazardous
2. Irritant (skin and eye - cat 2)
3. Corrosive (skin - cat 1A)
4. Corrosive (to metals cat - 1)

Example 2: extreme pH-value, but without high corrosivity potential

The example material is a mixture having an extreme pH-value. But the ingredients causing the extreme pH are all non-corrosive except one component classified only Class 8 Packing Group III in high concentrated solutions, although the pH-value is more extreme than in the example material. This proves that the extreme pH is no sufficient indicator for skin corrosivity and that assignment of Packing Group II for such mixtures and solutions according the proposed 2.8.4.4 is justified.

Example 2: Cleaner for industrial application

Formulation				
Hazardous component	CAS no.	Content	Classification according GHS	Classification acc. 67/548/EEC
Alcohols, C12 C14, ethoxylated, sulfates, sodium salts	68891-8-3	1 - 5%	Skin Irr. 2, H315 Eye Dam. 1, H318	Xi, irritant, R38, R41
Trissodium nitrilotriacetat	5064-31-3	5 - 10%	Acute Tox. 4, H302 Eye Irr. , H319 Carc. 2, H351	Carcinogenic, category 3, R40 Xi, irritant, R36 Xn, harmful, R22
Fatty alcohol ethoxylate C10 iso5EO	61827-42-7	1 - 5%	Acute Tox. 4, H302 Eye Dam. 1, H318	Xi, irritant, R41
Silicic acid, potassium salt, molar ratio (SiO_2/K_2O) <= 1,6	1312-76-1	1 - 3%	Skin Corr. 1B, H314 Eye Dam. 1, H318	C, corrosive, R34

pH-value	Measured material:
pH-value: 11,9	100 % product
pH-value: 10,5-11,5	1% solution in demineralized water

Ingredients
All ingredients except the Silicic acid potassium salt are non-corrosive. The silicic acid potassium salt has to be considered corrosive in concentrations above 10 %. Even taking into consideration synergistic effects of the other components assignment of Packing Group I for a maximum content of 3 % is not justified.

Examples 3 and 4: extreme pH-value, but without corrosive ingredients

The example materials are solutions or mixtures having an extreme pH-value. But the ingredients causing the extreme pH are all non-corrosive according transport regulations, although the pH-value of the pure substance is more extreme than in the preparations. This proves that the extreme pH is no sufficient indicator for skin corrosivity and that assignment of Packing Group II for such mixtures and solutions according the proposed 2.8.4.4 is justified.

Example 3: Cleaner for automotive

Formulation				
Hazardous component	CAS no.	Content	Classification according GHS	Classification acc. 67/548/EEC
Trissodium nitrilotriacetat	5064-31-3	10 - 25%	Acute Tox. 4, H302 Eye Irr. 2, H319 Carc. 2, H351	Carcinogenic, category 3, R40 Xi, irritant, R36 Xn, harmful, R22
Isotridecanol, ethoxylated	69011-36-5	1 - 5%	Acute Tox. 4, H302 Eye Dam. 1, H318	Xi, irritant, R41
Alcohols, C12-C14 ethoxylated	68891-38-3	1 - 5%	Skin Irr. 2, H315 Eye Dam. 1, H318	Xi, irritant, R38, R41

pH-value	Measured material:
pH-value: 11,3 – 12,7	10 % solution in demineralized water

Ingredients
All ingredients are non-corrosive. Even taking into consideration synergistic effects of the other components, the assignment of Packing Group I is not justified.

Example 4: Etching agents for metals

Formulation				
Hazardous component	CAS no.	Content	Classification according GHS	Classification acc. 67/548/EEC
oxalic acid	144-62-7	60 - 80%	Acute Tox. 4, H302 Acute Tox. 4, H312	Xn, harmful, R21/22
Sodium3-nitrobenzenesulphonate	127-68-4	1 - 5%	Skin Sens. 1, H317 Eye Irr. 2. , H319	Xi, irritant, R36, R43

pH-value	Measured material:
pH-value: 1,1 – 1,8	1% product solved in demineralized water

Ingredients
All ingredients are non-corrosive. Even taking into consideration synergistic effects of the other components, the assignment of Packing Group I is not justified.

Annex III

Overview of packing instructions for corrosive n.o.s. entries without subrisk

UN-no.	Proper shipping name	UN packing group I			UN packing group II			UN packing group III		
		Packa-gings	IBC	Tanks	Packa-gings	IBC	Tanks	Packa-gings	IBC	Tanks
1760	Corrosive liquid, n.o.s.	P001	--	T14 (TP2, TP27)	P001	IBC02	T11 (TP2, TP27)	P001	IBC03 LP01	T7 (TP2)
1719	Caustic alkali liquid, n.o.s.	PG not assigned			P001	IBC02	T11 (TP2, TP27)	P001	IBC03	T7 (TP1, TP28)
1740	Hydrogendifluorides, solid, n.o.s.	PG not assigned			P002	IBC08 B2, B4	T3 (TP33)	P002	IBC08 B3	T1 (TP33)
1759	Corrosive solid, n.o.s.	P002	IBC07 (B1)	T6	P002	IBC08 B2, B4	T3 ((TP33)	P002	IBC08 LP02, B3	T1 (TP33)
1903	Disinfectant, liquid, corrosive, n.o.s.	P001	--	--	P001	IBC02	--	P001	IBC03 LP01	--
2735	Amines, liquid, corrosive, n.o.s.	P001	--	T14 (TP2, TP27)	P001	IBC02	T11 (TP1, TP27)	P001	IBC03 LP01	T7 (TP1, TP28)
2801	Dye, liquid, corrosive, n.o.s.									
2987	Chlorosilanes, corrosive, n.o.s.	PG not assigned			P010	--	T14 (TP2, TP7, TP13, TP27)	PG not assigned		
3244	Solids containing corrosive liquid, n.o.s.	PG not assigned			P002 (PP9)	IBC05	T3 (TP33) BK1, BK2	PG not assigned		
3147	Dye, solid, corrosive, n.o.s.	P002	IBC07 B1	T6 (TP33)	P002	IBC08 B2, B4	T3 (TP33)	P002	IBC08 LP02, B3	T1 (TP33)
3259	Amines, solid, corrosive, n.o.s.									
3260	Corrosive, solid, acidic, inorganic, n.o.s.									
3261	Corrosive, solid, acidic, organic, n.o.s.									
3262	Corrosive solid, basic, inorganic, n.o.s.									
3263	Corrosive solid, basic, organic, n.o.s.									

UN-no.	Proper shipping name	UN packing group I			UN packing group II			UN packing group III		
		Packa-gings	IBC	Tanks	Packa-gings	IBC	Tanks	Packa-gings	IBC	Tanks
3264	Corrosive liquid, acidic, inorganic, n.o.s.	P001	--	T14 (TP2, TP27)	P001	IBC02	T11 (TP2, TP27)	P001	IBC03 LP01	T7 (TP1, TP28)
3265	Corrosive liquid, acidic, organic, n.o.s.									
3266	Corrosive liquid, basic, inorganic, n.o.s.									
3267	Corrosive liquid, basic, organic, n.o.s.									