

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

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**Sub-Committee of Experts on the  
Transport of Dangerous Goods**

**Forty-second session**

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Item 8 (a) of the provisional agenda

**Issues relating to the Globally Harmonized System  
of Classification and labelling of chemicals:  
Corrosivity criteria**

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

**Twenty-fourth session**

Geneva, 12 – 14 December 2012

Item 4 (c) of the provisional agenda

**Implementation of GHS:  
Cooperation with other bodies or international  
organisations**

**Harmonisation of the skin corrosion classification criteria in  
the 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 working group on corrosivity criteria (see informal document INF.53 (TDG, 41st session) - INF.18 (GHS, 23<sup>rd</sup> session) and INF.27 (TDG, 41st session) - INF.11 (GHS, 23<sup>rd</sup> session) this document proposes to harmonise chapter 2.8 of the Model Regulations with GHS as follows:

- (a) To add GHS text into the Model Regulations;
- (b) To amend the criteria for the assignment of packing group I in order to reflect appropriate transport conditions for this packing group.

This results into the assignment of a packing group in two steps.

**Background**

1. The Joint TDG-GHS working group on corrosivity criteria agreed at its last two meetings during the 40th and the 41st sessions of the Sub-Committee of Experts on the Transport on Dangerous Goods (see informal document INF.51 (TDG, 40<sup>th</sup> session), that its objectives were:

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

## Introduction

2. The new text for inclusion in the Model Regulations is taken from the corresponding GHS text (as proposed by the informal correspondence group on the editorial revision of chapters 3.2 and 3.3) but, where necessary, adapted concerning numbering, terms (e.g. packing groups instead of categories) and scope (e.g. irritation criteria are not adopted). A comparison of the text of the Model Regulations with the GHS text is not included in this document but can be found in INF.27 (TDG, 41<sup>st</sup> session) - INF.11 (GHS, 23<sup>rd</sup> session).

3. During the discussion there was consensus in the Joint TDG-GHS Group that packing group I should be assigned only to substances posing a very high risk during transport. To achieve the assignment of proper transport conditions we propose to add additional criteria for the assignment of packing group I. These additional criteria are taken from sub-section 2.8.1.2 of the IMDG Code. These have been slightly modified in order to reflect that the risk may extend beyond the location of the incident.

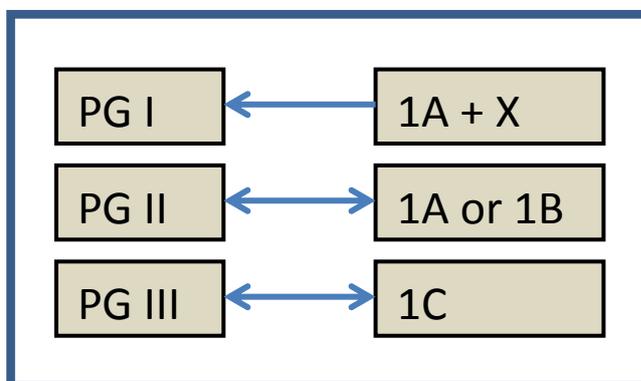
4. Packing group I would be assigned if the test data show total destruction of skin in 3 min or less exposure (i.e. GHS category 1A) and if the substance exhibits one of the following properties:

- (a) Sufficiently volatile to evolve corrosive vapour and/or produce toxic gases when decomposed by very high temperatures; and/or
- (b) Having additional systemic toxic properties; and/or
- (c) Becoming corrosive after having reacted with water, or with moisture in the air; accompanied by the liberation of corrosive gases. Such gases usually become visible as fumes in the air; and/or
- (d) Evolution of considerable heat in reaction with water leading to spattering of the material; and/or
- (e) Evolution of considerable heat in reaction with organic materials, including wood, paper, fibres, some cushioning materials and certain fats; and oils.

5. If none of the additional properties is present, packing group II is assigned, even if the skin is destroyed in less than 3 min (see revised table 2.8.2.5). GHS may consider implementing these additional classification criteria as well.

6. The criteria for the assignment of packing group III based on test data remains unchanged.

7. The following diagram illustrates the correspondence between TDG and GHS in the proposed approach, whereby "X" refers to the additional criteria listed in paragraph 4 above.



8. This document proposes a 2-step approach for the classification and the assignment of a packing group.
9. If validated test data (in vivo or in vitro) are available, the respective packing group (I, II) is assigned, as is currently done. In a second step, packing group I is amended into packing group II if the substance or mixture does not exhibit any of the properties listed in paragraph 4 above.
10. If alternative classification methods (e.g. bridging principles, additivity approach, non additivity approach (e.g. extreme pH-values), expert judgement etc.) are used, packing group II is assigned by default. But as a second step packing group II is amended into packing group I if the substance or mixture does exhibit one of the properties listed in paragraph 4 above.
11. In addition there are rules proposed to assign packing group III or classify as non-dangerous. GHS may consider assigning category 1 whenever an alternative method has been used. This would give even more information to the user, as they could directly distinguish between tested substances or mixtures and those classified using an alternative method.
12. Examples demonstrating the consequences of the proposed approach are shown in Annex I.
13. For the harmonisation of the transport regulations with the GHS, it is necessary also to harmonise with principles, which GHS is using, such as: weight of evidence and expert judgement. These changes to the Model Regulations are submitted in a separate paper (ST/SG/AC.10/C.3/2012/74).

## **Justification**

14. To determine proper transport conditions based on the hazard of substances or mixtures, additional criteria for the assignment of packing group I are required. For transport and for supply/use only those substances and mixtures which really can cause severe damage should be assigned to packing group I. With the introduction of additional considerations for packing group I this can be achieved.
15. On the other hand, alternative methods are not really sufficiently reliable to predict whether a product will destroy the skin e.g. within 3 min. Therefore a classification based on these methods should not be taken as such but should be subject to additional considerations. As the sub-category is not needed for the label in GHS, the classification into category 1 without sub-categorization is sufficient and could be applied for supply/use. If subcategories are needed for other purposes then the communication of the hazard (via the label and the Safety Data Sheet), the methods laid down in the transport regulations to assign a packing group (see paragraph 11) can be used instead.
16. Beside this, the classification criteria for the alternative methods are very conservative (e.g. cut-off limits for classification as corrosive to skin are 5% (additivity approach) or even 1% (non-additivity approach). Therefore they always provide a worst case classification.
17. The additivity approach is based on the classification of the ingredients. As we learnt during the discussion at the Sub-Committee meeting in June 2012 this information may vary from country to country and even within one country/region from supplier to supplier, based on the information available. And not always the strictest classification is correct. As the sub-categories are not needed for labelling within GHS, there may be the tendency to make a worst case classification for the ingredients. An example is the Annex

VI of the CLP-regulation (Regulation (EC) No. 1272/2008) in Europe. The classifications for corrosive to skin have been deduced from the classifications available from Directive 67/548/EEC, which is the predecessor of the CLP-regulation in Europe. The classification criteria in the EC directive are slightly different (there is no observation period) and 2 “subcategories” were available. These 2 subcategories (identified with the R-phrases R35 and R34) were translated into subcategory 1A and 1B. As a consequence, no substance with the subcategory 1C is listed in Annex VI of the CLP-regulation.

## Proposal

18. Amend Chapter 2.8 of the Model Regulations as follows:

### “CHAPTER 2.8

#### CLASS 8 – CORROSIVE SUBSTANCES

##### 2.8.1 Definition

2.8.1.1 *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.

2.8.1.2 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. This means that all available information bearing on the determination of skin corrosion is considered together, including the results of appropriate validated in vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

2.8.1.3 Allocation of substances listed in the Dangerous Goods List in Chapter 3.2 to the packing groups in Class 8 has been made on the basis of experience taking into account such additional factors as inhalation risk (see 2.8.2.3) and reactivity with water (including the formation of dangerous decomposition products). New substances, including mixtures, can be assigned to packing groups on the basis of the length of time of contact necessary to produce full thickness destruction of human skin in accordance with the criteria in 2.8.2. Liquids, and solids which may become liquid during transport, which are judged not to cause human skin shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.2.2 (c) (ii).

2.8.1.4 Substances and preparations of Class 8 are divided among the three packing groups according to their degree of risk 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.

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## 2.8.2 Assignment of packing groups for substances and mixtures based on test data

2.8.2.1 In assigning the packing group to a substance in accordance with 2.8.1.3, 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 or 435. A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430 or 431 may be considered not to be corrosive to skin for the purposes of these Regulations without further testing. Data obtained in accordance with OECD-test guidelines which results are not sufficient for assignment of the packing group leads to assignment of packing group II. This applies also if the assignment of the packing group is based on the use of the classification of other regulations like supply and use. *Not sure what this means and that it should be included*

2.8.2.2 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 min starting after the exposure time of 3 min or less and which fulfill at least one of the additional criteria in table 2.8.3 for packing group I which describes a dangerous effect beyond the location of exposure;
- (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-not more than 60 min;
- (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 min 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 aluminum 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 aluminum indicates the substance being tested is corrosive the follow up test on the other metal is not required.*

**Table 2.8.2.2: Table summarizing the criteria in 2.8.2.2**

Packing Group	Exposure time	Observation period	Effect
I	≤ 3 min	≤ 60 min	Full thickness destruction of intact skin and: (a) <u>sufficiently volatile to evolve corrosive vapour and/or;</u> (b) <u>produce toxic gases when decomposed by very high temperatures and/or;</u> (c) <u>having additional systemic toxic properties and/or;</u> (d) <u>becoming corrosive after having reacted with water, or with moisture in the air; accompanied by the liberation of corrosive gases. Such gases usually become visible as fumes in the air and/or;</u> (e) <u>evolution of considerable heat in reaction with water leading to spattering of the material and/or;</u> (f) <u>evolution of considerable heat in reaction with organic materials, including wood, paper, fibres, some cushioning materials and certain fats and oils.</u>
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 °C when tested on both materials

2.8.2.3 A substance or preparation meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC<sub>50</sub>) 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 2.6.2.4.1).

### **2.8.3 Assignment of packing group for mixtures using alternative methods**

#### 2.8.3.1 Bridging principles

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

#### 2.8.3.1.2 Dilution

If a tested 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 diluted mixture may be classified as equivalent to the original tested mixture. Alternatively, the method explained in 2.8.2 could be applied.

#### 2.8.3.1.3 Batching

The skin corrosion potential of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the

same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the skin corrosion potential of the untested batch has changed. If the latter occurs, a new assignment to packing group is necessary.

#### 2.8.3.1.4 Concentration of mixtures of the highest packing group

If a tested mixture classified in the highest Packing group for skin corrosion is concentrated, the more concentrated untested mixture should be assigned to the highest Packing group without additional testing.

#### 2.8.3.1.5 Interpolation within one packing group

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

#### 2.8.3.1.6 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 skin corrosion for A and C are available and substantially equivalent, i.e. they are in the same Packing group and are not expected to affect the skin corrosion potential of B.

If mixture (i) or (ii) is already classified based on test data, then the other mixture can be assigned to the same packing group.

#### 2.8.3.2 Additivity approach

2.8.3.2.1 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 values mentioned in tables 2.8.3.2.3 and 2.8.3.3.3. In these cases the mixture could be classified according to those data as occasion demands, 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 values mentioned in tables 2.8.3.2.3 and 2.8.3.3.3, testing of the mixture may be considered. In those cases the tiered weight of evidence strategy should be applied.

2.8.3.2.2 If there are data showing that (an) ingredient(s) may be corrosive at a concentration of  $\geq 1\%$  (corrosive), the mixture should be classified accordingly.

**Table 2.8.3.2.3: Concentration of ingredients of a mixture classified as skin-corrosive that would trigger classification of the mixture in Class 8 and assignment to packing Groups I, II and III**

<b><u>Sum of ingredients assigned to:</u></b>	<b><u>Concentration triggering classification of a mixture as:</u></b>
	<b><u>Skin corrosive and assignment of</u></b>
	<b><u>Packing group</u></b> (see note below)
<b><u>Packing group I, II or III</u></b>	<b><u>≥ 5%</u></b>

Note:

- In case the sum of packing group I ingredients is ≥ 5% the mixture should be assigned to packing group I.
- In case the sum of the packing group I ingredients is < 5% but the sum of packing group I and II is ≥ 5%, the mixture should be assigned to packing group II.
- Similarly, in case the sum of packing group I and II is < 5% but the sum of packing group I + II + III is ≥ 5% the mixture would be assigned to packing group III
- If information sufficient for assignment to a packing group is not available for all ingredients, packing group II is assigned, unless there is indication packing group I needs to be assigned (see 2.8.3.3.4)

2.8.3.3 Non-additivity approach

2.8.3.3.1 Particular care must be taken when classifying mixtures containing certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in 2.8.3.2 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 since pH will be a better indicator of corrosion than the concentration limits of Table 2.8.3.2.3 A mixture containing corrosive ingredients that cannot be classified based on the additivity approach shown in 2.8.3.2., due to chemical characteristics that make this approach unworkable, should be assigned to Packing group II if it contains ≥ 1% of a corrosive ingredient. Assignment of packing group to mixtures with ingredients for which the approach in Table 2.8.3.2.3 does not apply is summarized in Table 2.8.3.3.3 below.

2.8.3.3.2 In the absence of any other information, a mixture is considered corrosive [for PG assignment see 2.8.3.3.4] 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.

**Table 2.8.3.3.3: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification in Class 8, together with the appropriate assignment of packing group**

	<b><u>Concentration:</u></b>	<b><u>Mixture assigned to:</u></b>
<u>Acid with pH ≤ 2</u>	<u>≥ 1%</u>	<u>Packing group II<sup>a</sup></u>
<u>Base with pH ≥ 11.5</u>	<u>≥ 1%</u>	<u>Packing group II<sup>a</sup></u>
<u>Other corrosive ingredients</u>	<u>≥ 1%</u>	<u>Packing group II<sup>a</sup></u>

<sup>a</sup> for the assignment of the packing group see 2.8.3.3.4.

2.8.3.3.4 For the assignment of the packing group, the following procedure should be applied:

- (a) If classified using the non-additivity approach to be corrosive to skin the assignment should be packing group II, unless (b) applies;
- (b) Packing group I should be assigned if:
  - (i) The effects described in table 2.8.2.2 are observed, which lead clearly to an assignment to packing group I; or
  - (ii) The total weight of evidence supports that a more stringent assignment is necessary; or
  - (iii) There are ingredients in the mixture which have been assigned to packing group I in the Dangerous Goods List in Chapter 3.2 and the amount in the mixture is greater than or equal to 5%;
- (c) Packing group III can be assigned if:
  - (i) Most ingredients in the mixture are non corrosive or have a packing group assigned (which means with the revised rules as laid down above that they have been tested) and the sum of the ingredients which are assigned to packing group I and II is less than 5%; or
  - (ii) The total weight of evidence supports the less stringent assignment of packing group III;
- (d) Mixtures may be regarded as not being corrosive to skin if:
  - (i) Additional data for the non additivity approach are available (e.g. acid / base reserve) or most ingredients in the mixture are not corrosive to skin. The cut-off limit for corrosive ingredients in such a mixture is 5 %;
  - (ii) Most ingredients in the mixture are not corrosive to the skin. The cut-off limit for corrosive ingredients in such a mixture is 5%.”

## Annex I

To show the consequences of the proposed approach, here are some generic examples. There are multiple possibilities to combine the new criteria. The examples shown below are just showing some possibilities and not all.

### 1. Based on test data (see 2.8.2)

#### (a) Substance A:

Test data is showing the destruction of the skin below 3 min of exposure within 60 min (based on in vitro test) AND there is the generation of considerable heat in reaction with water which results in spattering of the material:

Classification/packing group assignment: class 8, PG I

*Justification: based on test data the criteria for packing group I (destruction of the skin in less than 3 min within 60 min) is fulfilled AND at least one of the additional criteria is fulfilled (in this case the generation of considerable heat in reaction with water, causing the spattering of the material).*

#### (b) Substance B:

Test data is showing the destruction of the skin below 3 min of exposure within 60 min (based on in vitro test). None of the additional criteria in 2.8.2.4 is fulfilled

Classification/packing group assignment: class 8, PG II

*Justification: based on test data the criteria for packing group II (destruction of the skin in less than 1 hour within 14 days) is fulfilled AND none of the additional criteria is fulfilled*

#### (c) Substance C:

Test data is showing the destruction of the skin between 3 and 60 min of exposure within 14 days (based on in vitro test) AND the contact with water is generating considerable heat in reaction with water leading to spattering of the material.

Classification/packing group assignment: class 8, PG II

*Justification: based on test data the criteria for packing group II (destruction of the skin in less than 1 hour within 14 days) is fulfilled. Although an additional criterion is fulfilled, this doesn't lead to the assignment of packing group I, because the exposure time is greater than 3 min.*

### 2. Based on alternative methods (see 2.8.3):

#### (a) Mixture D:

Contains 3 corrosive ingredients, total amount 15% (one PG II > 5%, two PG III).

Classification/packing group assignment: class 8, PG II

*Justification: Additivity approach: the cut-off limit for the classification as corrosive to skin in table 2.8.3.2.3 of 5% is exceeded. Because none of the additional criteria as described in table 2.8.2.2 is fulfilled and there is no information available on the packing group assigned to the ingredients packing*

*group II is assigned. This is possible because none of the criteria for packing group I in 2.8.3.3.4 is fulfilled.*

**(b) Mixture E:**

Contains 3 corrosive ingredients, total amount 20%, pH-value 13,7 No other information available

Classification/packing group assignment: class 8, PG II

*Justification: Non additivity approach: The mixture shows an extreme pH-value and therefore, based on expert judgement, the criteria in 2.8.3.3 apply. The assignment of packing group II is based on 2.8.3.3.4 (a).*

**(c) Mixture F:**

Contains 3 corrosive ingredients, all packing group III, total amount 15%

Classification/packing group assignment: class 8, PG III

*Justification: Additivity approach (2.8.3.2) the cut-off limit in table 2.8.3.2.3 of 5% is exceeded and according to the note packing group III is assigned.*

**(d) Mixture G:**

Contains 3 non-corrosive ingredients, total amount 50%, pH-value 1, acid capacity.

Classification: Non dangerous

*Justification: Although the pH-value of 1 is seen as an extreme pH-value, the additional information available (acid capacity, all ingredients non corrosive) leads the expert judgement that the mixture is not dangerous for transport.*

## Annex II

### Examples of mixtures with extreme pH-values, showing evidence not to be classified as corrosive to skin

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 as these mixtures show no evidence to be corrosive to skin..

#### **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 to the proposed 2.8.3.3.4 provides a sufficient level of safety.

The solution is used in dental applications for:

- Cementation of in-lays, on-lays, crowns, and bridges made from metal or metal-ceramics or veneered with composite
- Cementation of in-lays, on-lays, 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	Aq. 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):  <u>Conclusion:</u> 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 min 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)
	<u>Conclusion:</u> 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 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 Classification and Labelling 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 as Class 8 and assigned to 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 2.8.3.3.4 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
Trisodium nitrilotriacetate	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 <sub>2</sub> /K <sub>2</sub> O) <= 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

<b>Ingredients</b>
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 2.8.3.3.4 is justified.

**Example 3: Cleaner for automotive**

<b>Formulation</b>				
<b>Hazardous component</b>	<b>CAS no.</b>	<b>Content</b>	<b>Classification according GHS</b>	<b>Classification acc. 67/548/EEC</b>
Trisodium nitrilotriacetate	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

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

<b>Ingredients</b>
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**

<b>Formulation</b>				
<b>Hazardous component</b>	<b>CAS no.</b>	<b>Content</b>	<b>Classification according GHS</b>	<b>Classification acc. 67/548/EEC</b>
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

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

<b>Ingredients</b>
All ingredients are non-corrosive. Even taking into consideration synergistic effects of the other components, the assignment of packing group I is not justified.